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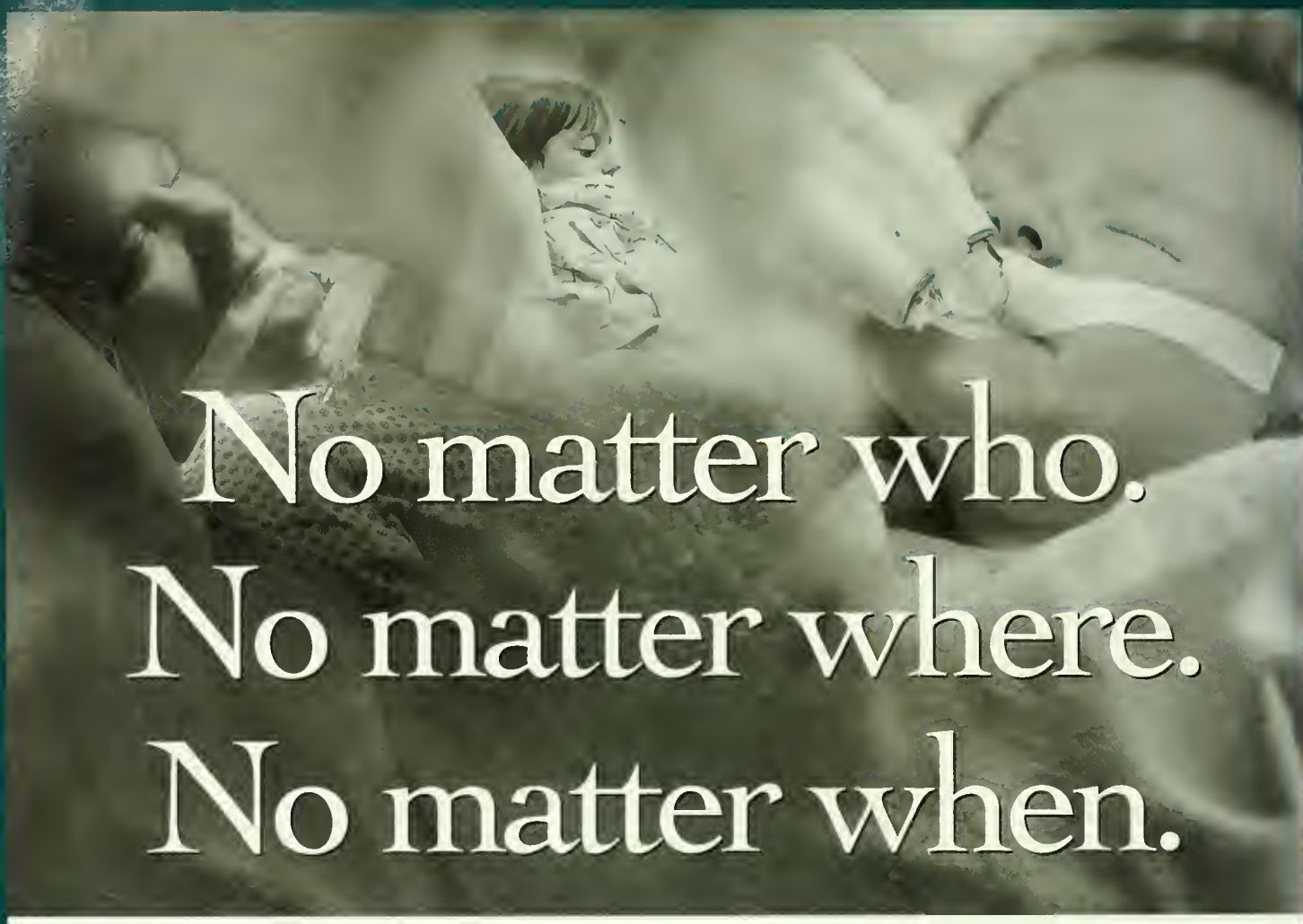

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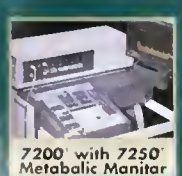
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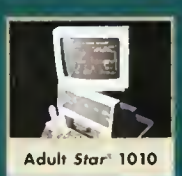
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Editorials, Commentaries, and Reviews To Note

The Association between Occupation and Tuberculosis: A Population-Based Survey (Article)—MT McKenna, M Hutton, G Cauthen, IM Onorato. Am J Respir Crit Care Med 1996;154(3)587-593. *See the related editorial:* ***Occupation and Tuberculosis: Questions that Need Answers****. GW Comstock. Am J Respir Crit Care Med 1996;154(3):553-554.*

Ethical Considerations of Ensuring an Informed and Autonomous Consent in Research Involving Critically Ill Patients (Commentary)—HJ Silverman. Am J Respir Crit Care Med 1996;154 (3):582-586.

The Relationship between Upper Respiratory Infections and Hospital Admissions for Asthma: A Time-Trend Analysis—SL Johnston, PK Pattemore, G Sanderson, S Smith, MJ Campbell, LK Josephs, et al. Am J Respir Crit Care Med 1996;154(3):654-660.

Risk Factors for Childhood Asthma and Wheezing: Importance of Maternal and Household Smoking—RI Ehrlich, DD Toit, E Jordaan, M Zwarenstein, P Potter, JA Volmink, E Weinberg. Am J Respir Crit Care Med 1996;154(3):681-688.

Pulmonary Function during the First Year of Life Following Acute Viral Bronchiolitis—IT Merth, JP de Winter, HM Zonderland, R Brand, PH Quanjer. Am J Respir Crit Care Med 1996;154(3):689-694.

Lung Function in Children and Adolescents with Occasional Exposure to Environmental Tobacco Smoke—GM Corbo, N Agabiti, F Forastiere, V Dell'Orco, R Pistelli, D Kriebel, et al. Am J Respir Crit Care Med 1996;154(3):695-700.

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Pediatric Thoracoscopy: A New Vista (State of the Art)—KM Bullard, NS Adzick. Pediatr Pulmonol 1996;22(2):129-135.

Comparison of Regularly Scheduled with As-Needed Use of Albuterol in Mild Asthma—JM Drazen, E Israel, HA Boushey, VM Chinchilli, JV Fahy, JE Fish, et al, for the National Heart, Lung, & Blood Institute's Asthma Clinical Research Network. N Engl J Med 1996; 335(12):841.

BACKGROUND: Inhaled β-agonists are the most commonly used treatment for asthma, but data suggest that regularly scheduled use of these agents may have a deleterious effect on the control of asthma. We compared the effects of regularly scheduled use of inhaled albuterol with those of albuterol used only as needed in patients with mild chronic, stable asthma. METHODS: In a multicenter, double-blind study, we randomly assigned 255 patients with mild asthma to inhale albuterol either on a regular schedule (126 patients) or only as needed (129 patients). The patients were followed for 16 weeks. RESULTS: The primary outcome indicator, peak expiratory air flow measured in the morning, did not change significantly during the treatment period in the scheduled (416 L/min after the run-in period and 414 L/min after the treatment period) or the as-needed (424 L/min at both times) treatment groups ($p = 0.71$). There were no significant differences between the 2 groups in peak flow variability, forced expiratory volume in one second, the number of puffs of supplemental albuterol needed, asthma symptoms, asthma quality-of-life score, or airway responsiveness to methacholine. The statistically significant differences between the groups in evening peak flow and in the short-term bronchodilator response to inhaled albuterol were small and judged to be clinically unimportant. CONCLUSIONS: In patients with mild asthma, neither deleterious nor beneficial effects derived from the regular use of inhaled albuterol beyond those derived from use of the drug as needed. Inhaled albuterol should be prescribed for patients with mild asthma on an as-needed basis. *See the related editorial:* ***Inhaled β_2-Agonists in the Treatment of Asthma—PM*** *O'Byrne, HAM Kerstjens. N Engl J Med 1996; 335(12):886-888.*

Decreased Imposed Work with a New Nasal Continuous Positive Airway Pressure Device—JF Klausner, AY Lee, AA Hutchison. Pediatr Pulmonol 1996;22(3):188.

This model study compared the imposed work of 2 nasal continuous positive airway pressure (NCPAP) devices for very low-birthweight (VLBW) babies: a new NCPAP device, designed by Moa et al, (Crit Care Med 16:1238, 1988), and a conventional NCPAP device. In addition, the variabilities in the pressures of a simulated airway were compared. A continuous flow (8 L/min) was used to generate CPAP. A Harvard ventilator was used to simulate breathing at a fixed volume (12.1 mL) and rate (45 breaths/min). The pressure drop across and the flow rate through each device were measured, thus allowing the determination of imposed work, ie, the work of breath-

ing done by the patient to overcome frictional losses due to the NCPAP device. In addition, the pressure fluctuations in the simulated airway were measured. The data presented are averages of 36 breaths using the new device and 34 breaths using the conventional device. The means of the imposed work in the new device and in the conventional device were 0.135 (95% CI ± 0.004) mJ/breath and 0.510 (95% CI ± 0.004) mJ/breath ($p < 0.01$) respectively. The coefficients of variation for pressure in the simulated airway were: new 6.8% and conventional 15.3%. We conclude that the imposed work of the new NCPAP device for the VLBW baby is approximately one-fourth of that of the conventional device. The airway pressure generated by the VLBW size of the new NCPAP device shows less variability during simulated breathing than that found with the conventional device. The findings support the clinical use of the new NCPAP device in the very low-birthweight baby.

End-Tidal Estimates of Arterial P_{CO_2} for Cardiac Output Measurement by CO_2 Rebreathing: A Study in Patients with Cystic Fibrosis and Healthy Controls—P Pianosi, J Hochman. Pediatr Pulmonol 1996;22(3):154.

We set out to determine the effects of various estimates of arterial P_{CO_2} (P_{aCO_2}) on calculation of cardiac output (Q) by the indirect Fick (CO_2) method in healthy children and children with cystic fibrosis (CF), and to develop a prediction equation for children for P_{aCO_2}, based on end-tidal P_{CO_2} (P_{etCO_2}). The study had 3 parts: (1) 23 healthy children exercised lightly and moderately while arterialized capillary blood gases and P_{etCO_2} were measured simultaneously so that a prediction equation for P_{aCO_2} could be derived from P_{etCO_2}. Cardiac output was measured by CO_2 rebreathing at each workload; different values for P_{aCO_2} (measured in arterialized capillary blood, end-tidal, and P_{aCO_2} derived from the Bohr equation assuming normal dead space) were used to calculate Q; (2) our equation $P_{aCO_2} = 0.647\ P_{etCO_2} + 12.4$ was tested prospectively to measure Q in 9 healthy children; and (3) cardiac output based on arterialized capillary P_{aCO_2} was compared with that based on Jones-corrected P_{etCO_2} during light and moderate exercise in 16 CF patients whose forced expiratory volume in 1 second (FEV_1) ranged from normal to 37% predicted. Our results have shown that *in healthy children* end-tidal based-estimates of P_{aCO_2} tended to overestimate Q, whereas P_{aCO_2} values derived by the Bohr equation and assuming normal dead space tended to underestimate Q, compared with Q calculated from directly measured P_{aCO_2}. Our prediction equation resulted in good agreement compared with directly measured P_{aCO_2} when used to calculate Q (mean difference, +1.3%; range, +9% to −13%). *CF patients* with little or no airway obstruction had results similar to healthy controls, but those with severe airway obstruction had lower values for Q when P_{etCO_2} was used instead of directly measured P_{aCO_2}. We conclude that estimates of P_{aCO_2} from P_{etCO_2} are not reliable in patients with moderately severe pulmonary disease due to CF. In healthy children, the prediction equation for P_{aCO_2} from P_{etCO_2} derived in the present study gives results superior to other bloodless methods currently in use for computation of Q by the indirect Fick (CO_2) method.

Effect of Tracheal Gas Insufflation on Demand Valve Triggering and Total Work during Continuous Positive Airway Pressure Ventilation—JD Hoyt, JJ Marini, A Nahum. Chest 1996;110 (3):775.

Tracheal gas insufflation (TGI) improves CO_2 clearance and may reduce work of breathing by lowering the required minute ventilation ($\dot{V}_E$). However, TGI might also impair the ability to trigger the ventilator, because to lower external circuit pressures, inspiratory effort must outstrip catheter flow rate ($\dot{V}_c$) and overcome the dynamic hyperinflation caused by TGI. We studied these effects using a 2-chamber lung model of the respiratory muscles (RM) and lungs (L). The RM-chamber was ventilated using a sinusoidal flow pattern with a tidal volume (V_T) of 0.5 L at various peak inspiratory flow rates ($\dot{V}_{pk}$) to simulate differences in effort intensity. The L-chamber was connected to a 60-L/min continuous flow circuit with a 10 cm H_2O positive end-expiratory pressure valve and to 3 different ventilator demand valve circuits, each set at continuous positive airway pressure (CPAP) of 10 cm H_2O. We used continuous TGI at 0, 2.5, 5, 10, and 15 L/min. The work of triggering (W-trig) increased with increasing $\dot{V}_c$ and decreased with increasing $\dot{V}_{pk}$. The L-ventilator failed to trigger when $\dot{V}_c$ was 15 L/min and $\dot{V}_{pk}$ was 20 L/min. At a fixed $\dot{V}_E$, the effect of TGI on total mechanical inspiratory work (W-tot) was relatively small and varied among the different CPAP systems used. We conclude that weak patients may fail to open the demand valve of the CPAP system during TGI at high catheter flow rates. The net effect of TGI on the effort made by ventilated patients would depend not only on the interactions between TGI and the ventilator, but also on the efficiency of TGI in decreasing dead-space and lowering the $\dot{V}_E$ requirement.

Risk of Pulmonary Complications after Elective Abdominal Surgery—VA Lawrence, R Dhanda, SG Hilsenbeck, CP Page. Chest 1996;110 (3):744.

OBJECTIVE: Intra-abdominal operations are relatively high risk for pulmonary complications. Previous research has more intensely investigated cardiac operative risk, but recent work suggests that significant pulmonary complications may be more

common than cardiac complications and associated with longer length of stay. This study identified risk indicators for pulmonary complications after elective abdominal operations. DESIGN: Nested case-control. SETTING: University affiliated Veterans Affairs hospital. PATIENTS: We used a computerized registry of all 2,291 patients undergoing elective abdominal operations from 1982 to 1991. Ascertainment and verification of pulmonary and cardiac complications were systematic and explicit. Charts of all 116 patients identified by the registry as having complications and 412 (19%) randomly selected from 2,175 remaining patients were reviewed to verify complications, using explicit criteria and independent abstraction of preoperative and postoperative components of charts. From 528 validated subjects (23% of the cohort), 82 cases and 82 control subjects were closely matched by operation type and age, ± 10 years. MEASUREMENTS & RESULTS: The primary outcome measure was postoperative pulmonary complications. Among 82 cases with pulmonary complications, 27 (33%) also had cardiac complications. Preoperative variables independently associated with pulmonary complications by multivariable analysis ($p \leq 0.05$) included the following: Charlson comorbidity index (per point odds ratio [OR], 1.6; 95% confidence interval [CI], 1.004 to 2.6), Goldman cardiac risk index (per point OR, 2.04; 95% CI, 1.17 to 3.6), abnormal chest radiograph (OR, 3.2; 95% CI, 1.07 to 9.4), and abnormal findings on lung examination (OR, 5.8; 95% CI, 1.04 to 32). Equal proportions of cases and control subjects had preoperative diagnostic spirometry. No component of spirometry predicted complications, including severity of obstructive lung disease. CONCLUSIONS: For pulmonary operative risk, abnormal results of lung examination and chest radiography plus cardiac and overall comorbidity were important. Spirometry was not helpful. Because 33% of cases had both cardiac and pulmonary complications, future studies should prospectively examine comparative incidence, outcomes, and predictors of both types of complications. *See the related editorial:* ***Pulmonary Function Tests before Surgery****—DS Macpherson. Chest 1996;110(3):587-589.*

Noninvasive Positive-Pressure Ventilation Via Face Mask during Bronchoscopy with BAL in High-Risk Hypoxemic Patients—M Antonelli, G Conti, L Riccioni, GU Meduri. Chest 1996; 110(3):724

OBJECTIVE: The aim of this study was to assess the feasibility and safety of noninvasive positive-pressure ventilation (NPPV) via a face mask to aid in performing fiberoptic bronchoscopy (FOB) with BAL in immunosuppressed patients with gas exchange abnormalities that contraindicate using conventional unassisted FOB. POPULATION: Eight consecutive immunosuppressed patients (40 ± 14 years old) with suspected pneumonia entered the study. Entrance criteria included the following: (1) P_{aO_2}/fraction of inspired oxygen (F_{IO_2}) of 100 or less; pH of 7.35 or more; and (3) improvement in O_2 saturation during NPPV before initiating FOB. INTERVENTION: Patients had routine application of topical anesthesia to the nasopharynx. A full face mask was connected to a ventilator (Servo 900C; Solna, Sweden) set to deliver continuous positive airway pressure (CPAP) of 4 cm H_2O, pressure support ventilation of 17 cm H_2O, and 1.0 F_{IO_2}. The mask was secured to the patient with head straps. NPPV began 10 minutes before starting FOB and continued for 90 minutes or more after the procedure was completed. The bronchoscope was passed through a T-adapter and advanced through the nose. BAL was obtained by sequential instillation and aspiration of 5 to 25 mL aliquots of sterile saline solution through a bronchoscope wedged in a radiographically involved subsegment. Oxygen saturation, heart rate, respiratory rate, and arterial blood gases were monitored during the study. RESULTS: NPPV significantly improved P_{aO_2}/F_{IO_2} and O_2 saturation. FOB with NPPV was well tolerated, and no patient required endotracheal intubation. A causative pathogen was identified by BAL in all patients. Six patients responded to treatment and survived hospital admission. Two patients died 5 to 7 days after FOB from unrelated complications of the underlying illness. CONCLUSIONS: NPPV should be considered during bronchoscopy of immunosuppressed patients with severe hypoxemia.

Noninvasive Positive Pressure Ventilation in Status Asthmaticus—GU Meduri, TR Cook, RE Turner, M Cohen, KV Leeper. Chest 1996;110 (3):767.

OBJECTIVE: In asthmatic patients with acute respiratory failure (ARF), placing an endotracheal tube is associated with a high rate of complications and results in increased airway resistance. In acute asthma, mask-continuous positive airway pressure (CPAP) decreases airway resistance and the work of breathing (WOB), but does not improve gas exchange. In COPD with ARF, adding intermittent positive pressure ventilation to mask-CPAP results in an additional improvement in WOB and is highly effective in correcting gas exchange abnormalities. In our medical ICU, noninvasive positive pressure ventilation (NPPV) is used as first-line interventional therapy in eligible patients with hypercapnic ARF. We report our experience with NPPV in 17 episodes of asthma and ARF over a 3-year period. METHODS: A face mask was secured with head straps, avoiding a tight fit, and connected to a ventilator (PB-7200). Initial ventilatory settings included CPAP at 4 ± 2 cm H_2O to offset intrinsic positive end-expiratory pressure and pressure support ventilation (PSV) at 14 ± 5 cm H_2O aiming at a respiratory rate < 25 breaths/min and an exhaled tidal volume of 7 mL/kg or more. PSV was then adjusted following arterial blood gas results. RESULTS: Mean age was 35.4 ± 11.3 years; 10 patients were female. The mean (± SE) for different physiologic values are reported at initiation, < 2 hours, 2 to 6 hours, and 12 to 24 hours into NPPV. pH was 7.25 ± 0.01, 7.32 ± 0.02 ($p = 0.0012$), 7.36 ± 0.02 ($p < 0.0001$), and 7.38 ± 0.02; P_{aCO_2} was 65 ± 2, 52 ± 3 ($p = 0.002$), 45 ± 3 ($p < 0.0001$), and 45 ± 4; P_{aO_2} fraction of inspired oxygen was 315 ± 41, 403 ± 47, 367 ± 47, and 472 ± 67 ($p = 0.06$); and respiratory rate was: 29.1 ± 1, 22 ± 1 ($p < 0.0001$), 20 ± 1, and 17 ± 1. NPPV was well tolerated, and only 2 patients required sedation. Initial delivered minute ventilation was 16 ± 4 L/min. The mean (± SD) peak inspiratory pressure to ventilate in the NPPV-treated patients was 18 ± 5 cm H_2O and always < 25 cm H_2O. There was no complication or problem with expectorating of secretions. Oral intake (liquid diet) was preserved. Two patients required intubation (35 min and 89 h into NPPV) for worsening P_{aCO_2}. Duration of NPPV was 16 ± 21 hours. All patients survived. Length of hospital stay was 5 ± 4 days. CONCLUSIONS: In asthmatic patients with ARF, NPPV via a face mask appears highly effective in correcting gas exchange abnormalities using a low inspiratory pressure (< 25 cm H_2O). A randomized study is in progress to assess fully the role of NPPV in status asthmaticus.

Asthma Deaths Confounded by Substance Abuse: An Assessment of Fatal Asthma—T Levenson, PA Greenberger, ER Donoghue, BD Lifschultz. Chest 1996;110(3):604.

BACKGROUND: The Chicago region has been identified as having a very high death rate from asthma in patients aged 5 to 34 years. We investigated circumstances surrounding the fatal attack to determine whether the death was from asthma, of indeterminate cause, or coincidental to asthma. METHODS: Cases of asthma deaths from the Office of the Medical Examiner, where the deceased were younger than 46 years of age, were used to determine clinical, toxicologic, and pathologic findings relevant to asthma. Toxicologic results were compared with homicide victims. RESULTS: From 102 cases of fatal asthma, 46 cases were classified as deaths from asthma and 17 cases were considered probably from asthma as toxicologic tests were negative. Twenty-three cases were of indeterminate cause in that the acute respiratory symptoms were accompanied by substance use or alcohol consumption. Fourteen cases were not caused by asthma but were substance related, primarily cocaine. Overall, 29 of 92 (31.5%) cases were confounded by substance abuse or alcohol ingestion, which is almost as high as in homicide victims (38/82 [46.3%]). Mucus plugging of bronchi and or hyperinflation in fatal asthma occurred in 65 of 93 (69.9%) cases. Anti-inflammatory medications were being utilized by just 2 patients. Sufficient information was available to identify potentially fatal asthma in 6 of 20 cases (30%). CONCLUSION: Some of the re-

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ported rise in asthma deaths is a reflection of substance use or alcohol consumption similar to that seen in victims of homicide. In that patients with asthma are hypersensitive to α-adrenergic agonists, the use of cocaine may be especially dangerous and induce fatal ventricular dysrhythmias.

A Comparison of Ipratropium and Albuterol vs Albuterol Alone for the Treatment of Acute Asthma—JP Karpel, EN Schacter, C Fanta, D Levey, P Spiro, T Aldrich, SS Menjoge, TJ Witek. Chest 1996;110(3):611.

To evaluate the role of inhaled ipratropium bromide in acute asthma, a double-blind study of 384 emergency department patients compared the effect of the combination of ipratropium and albuterol with that of albuterol alone. Patients were randomized to receive nebulizer treatments with either 2.5 mg of albuterol or 2.5 mg of albuterol mixed with 0.5 mg of ipratropium bromide at entry and at 45 minutes. Spirometry, vital signs, and oxygen saturation were measured before and at 45 and 90 minutes following the nebulizer treatments. Serum potassium levels were obtained at entry and 90 minutes. The 2 groups did not differ significantly in age (mean ± SD = 33.4 ± 9.3 and 32.5 ± 9.7 years for the albuterol and ipratropium group and the albuterol group, respectively), baseline FEV_1 (mean ± SD = 1.22 ± 0.42 and 1.25 ± 0.44 L respectively), or prior use of asthma medications. At 45 minutes, there were significantly more responders (15% increase in FEV_1 over baseline) in the group receiving albuterol and ipratropium compared with albuterol and saline solution (85% and 78%, respectively; $p = 0.045$), but the median change in FEV_1 from baseline did not differ (0.530 L for the albuterol and ipratropium group and 0.420 L for the albuterol and saline solution group; $p = 0.347$). By 90 minutes, the percentage of responders did not differ (88% and 89%, respectively), and the median change in FEV_1 was 0.680 L for the group receiving albuterol and ipratropium and 0.650 L for the group receiving albuterol and saline solution ($p = 0.693$). There were no significant adverse events experienced by patients in either group. Furthermore, there were no significant differences in the number of patients requiring additional therapy in the emergency department or hospitalization. We conclude that in this population of inner city asthmatics, we were unable to demonstrate significant additive benefit of nebulized ipratropium bromide to nebulized albuterol.

Short-Term Effects of Inhaled β-Adrenergic Agonist on Breathlessness and Central Inspiratory Drive in Patients with Nonreversible COPD—JM Pino-García, F García-Río, L Gómez, MA Racionero, S Díaz-Lobato, J Villamor. Chest 1996;110(3):637.

In patients with COPD, a relationship between breathlessness and respiratory effort, assessed in terms of mouth occlusion pressure ($P_{0.1}$) has been described. To evaluate the short-term effects of inhaled terbutaline on breathlessness, breathing pattern, and $P_{0.1}$ in patients with nonreversible COPD, we designed a randomized, double-blind, parallel, placebo-controlled study. Twenty-five patients with stable nonreversible COPD, mean age 64 ± 11 years, were enrolled in the study. Patients received 500 μg inhaled terbutaline or placebo. Breathlessness, using the Borg scale, breathing pattern, and $P_{0.1}$ were measured at baseline and 30 minutes after inhalation. Terbutaline resulted in a significant decrease in Borg scale, while no differences were observed after placebo. No significant changes in breathing pattern were found. Nevertheless, a decrease in $P_{0.1}$ (0.31 ± 0.07 vs 0.21 ± 0.05 kPa; $p < 0.001$) after terbutaline inhalation was observed. Borg score was correlated with $P_{0.1}$ in all patients. Moreover, changes in Borg score after medication were directly proportional to $P_{0.1}$ changes ($r = 0.85$; $p < 0.01$). We conclude that terbutaline decreases central inspiratory drive and improves breathlessness in patients with nonreversible COPD.

Effects of Cigarette Smoking on Lung Function in Adolescent Boys and Girls—DR Gold, X Wang, D Wypij, FE Speizer, JH Ware, DW Dockery. N Engl J Med 1996;335(13):931.

BACKGROUND: Little is known about the sex-specific effects of cigarette smoking on the level and growth of lung function in adolescence, when 71% of people in the United States who smoke tried their first cigarette. METHODS: We studied the effects of cigarette smoking on the level and rate of growth of pulmonary function in a cohort of 5,158 boys and 4,902 girls 10 to 18 years of age, examined annually between 1974 and 1989 in 6 cities in the United States. RESULTS: We found a dose-response relation between smoking and lower levels of both the ratio of forced expiratory volume in 1 second to forced vital capacity (FEV_1/FVC) and the forced expiratory flow between 25 and 75% of FVC (FEF_{25-75}). Each pack per day of smoking was associated with a 3.2% reduction in FEF_{25-75} for girls ($p = 0.01$) and a 3.5% reduction in FEF_{25-75} for boys ($p = 0.007$). Whereas the FVC level was elevated in smokers, the rate of growth of FVC and FEV_1 was reduced. Among adolescents of the same sex, smoking 5 or more cigarettes a day, as compared with never smoking, was associated with 1.09% slower growth of FEV_1 per year in girls (95% confidence interval, 0.70 to 1.47%) and 0.20% slower growth in boys (95% confidence interval, −0.16 to 0.56%), and with 1.25% slower growth of FEF_{25-75}/year in girls (95% confidence interval, 0.38 to 2.13%) and 0.93% slower growth in boys (95% confidence interval, 0.21 to 1.65%). Whereas girls who did not smoke reached a plateau in lung function at 17 to 18 years of age, girls of the same age who smoked had a decline of FEV_1 and FEF_{25-75}. CONCLUSIONS: Cigarette smoking is associated with evidence of mild airway obstruction and slowed growth of lung function in adolescents. Adolescent girls may be more vulnerable than boys to the effects of smoking on the growth of lung function.

Effect of Theophylline on Sleep-Disordered Breathing in Heart Failure—S Javaheri, TJ Parker, L Wexler, JD Liming, P Lindower, GA Roselle. N Engl J Med 1996;335:562.

BACKGROUND: Theophylline has been used to treat central apnea associated with Cheyne-Stokes respiration (periodic breathing). We studied the effect of short-term oral theophylline therapy on periodic breathing associated with stable heart failure due to systolic dysfunction. METHODS: Fifteen men with compensated heart failure (left ventricular ejection fraction, 45% or less) participated in the study. Their baseline polysomnograms showed periodic breathing, with more than 10 episodes of apnea and hypopnea/hour. In a double-blind crossover study, the patients received theophylline or placebo orally twice daily for 5 days, with 1 week of washout between the 2 periods. RESULTS: After 5 days of treatment, the mean (±SD) plasma theophylline concentration was 11 ± 2 μg/mL. Theophylline therapy resulted in significant decreases in the number of episodes of apnea and hypopnea/hour (18 ± 17, vs 37 ± 23 with placebo and 47 ± 21 at baseline; $p < 0.001$), the number of episodes of central apnea/hour (6 ± 14, vs 26 ± 21 and 26 ± 20, respectively; $p < 0.001$), and the percentage of total sleep time during which the arterial oxyhemoglobin saturation was < 90% (6 ± 11%, vs 23 ± 37 and 14 ± 14%, respectively; $p < 0.04$). There were no significant differences in the characteristics of sleep, the frequency of ventricular arrhythmias, daytime arterial-blood gas values, or the left ventricular ejection fraction during the baseline, placebo, and theophylline phases of the study. CONCLUSIONS: In patients with stable heart failure, oral theophylline therapy reduced the number of episodes of apnea and hypopnea and the duration of arterial oxyhemoglobin desaturation during sleep.

Differences in 4-Year Health Outcomes for Elderly and Poor, Chronically Ill Patients Treated in HMO and Fee-for-Service Systems: Results from the Medical Outcomes Study—JE Ware Jr, MS Bayliss, WH Rogers, M Kosinski, AR Tarlov. JAMA 1996;276(13):1039.

OBJECTIVE: To compare physical and mental health outcomes of chronically ill adults, including elderly and poor subgroups, treated in health maintenance organization (HMO) and fee-for-service (FFS) systems. STUDY DESIGN: A 4-year observational study of 2,235 patients (18 to 97 years of age) with hypertension, non-insulin-dependent diabetes mellitus (NIDDM), recent acute myocardial infarction, congestive heart failure,

and depressive disorder sampled from HMO and FFS systems in 1986 and followed up through 1990. Those aged 65 years and older covered under Medicare and low-income patients (200% of poverty) were analyzed separately. SETTING & PARTICIPANTS: Offices of physicians practicing family medicine, internal medicine, endocrinology, cardiology, and psychiatry, in HMO and FFS systems of care. Types of practices included both prepaid group (72% of patients) and independent practice association (28%) types of HMOs, large multispecialty groups, and solo or small, single-specialty practices in Boston, Chicago, and Los Angeles. OUTCOME MEASURES: Differences between initial and 4-year follow-up scores of summary physical and mental health scales from the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) for all patients and practice settings. RESULTS: On average, physical health declined and mental health remained stable during the 4-year follow-up period, with physical declines larger for the elderly than for the nonelderly ($p < 0.001$). In comparisons between HMO and FFS systems, physical and mental health outcomes did not differ for the average patient; however, they did differ for subgroups of the population differing in age and poverty status. For elderly patients (those aged 65 years and older) treated under Medicare, declines in physical health were more common in HMOs than in FFS plans (54% vs 28%; $p < 0.001$). In 1 site, mental health outcomes were better ($p < 0.05$) for elderly patients in HMOs relative to FFS but not in 2 other sites. For patients differing in poverty status, opposite patterns of physical health ($p < 0.05$) and for mental health ($p < 0.001$) outcomes were observed across systems; outcomes favored FFS over HMOs for the poverty group and favored HMOs over FFS for the nonpoverty group. CONCLUSIONS: During the study period, elderly and poor chronically ill patients had worse physical health outcomes in HMOs than in FFS systems; mental health outcomes varied by study site and patient characteristics. Current health care plans should carefully monitor the health outcomes of these vulnerable subgroups.

The Effects of Patient Volume and Level of Care at the Hospital of Birth on Neonatal Mortality—CS Phibbs, JM Bronstein, E Buxton; RH Phibbs. JAMA 1996;276(13):1054.

OBJECTIVE: To examine the effects of neonatal intensive care unit (NICU) patient volume and the level of NICU care available at the hospital of birth on neonatal mortality. DESIGN: Birth certificate data linked to infant death certificates and to infant discharge abstracts were used in a logistic regression model to control for differences in each patient's clinical and demographic risks. Hospitals were classified by the level of NICU care available (no NICU: level I; intermediate NICU: level II; expanded intermediate NICU: level II+; tertiary NICU: level III) and by the average patient census in the NICU. SETTING: All nonfederal hospitals in California with maternity services. PATIENTS: All births in nonfederal hospitals in California in 1990 (n = 594,104), 473,209 (singletons only) of which were successfully linked with discharge abstracts. Of these infants, 53,229 were classified as likely NICU admissions. MAIN OUTCOME MEASURES: Death within the first 28 days of life, or within the first year of life, if continuously hospitalized. RESULTS: Patient volume and level of NICU care at the hospital of birth both had significant effects on mortality. Compared with hospitals without an NICU, infants born in a hospital with a level III NICU with an average NICU census of at least 15 patients/day had significantly lower risk-adjusted neonatal mortality (odds ratio, 0.62; 95% confidence interval, 0.47-0.82; $p = 0.002$). Risk-adjusted neonatal mortality for infants born in smaller level III NICUs, and in level II+ and level II NICUs, regardless of size, was not significantly different from hospitals without an NICU, and was significantly higher than hospitals with large level III NICUs. CONCLUSIONS: Risk-adjusted neonatal mortality was significantly lower for births that occurred in hospitals with large (average census, >15 patients/day) level III NICUs. Despite the differences in outcomes, costs for the birth of infants born at hospitals with large level III NICUs were not more than those for infants born at other hospitals with NICUs. Concentration of high-risk deliveries in urban areas in a smaller number of hospitals that could provide level III NICU care has the potential to decrease neonatal mortality without increasing costs.

Effects of Motion on the Performance of Pulse Oximeters in Volunteers—SJ Barker, NK Shah. Anesthesiology 1996;85(4):774.

BACKGROUND: Pulse oximetry is considered a standard of care in both the operating room and the postanesthetic care unit, and it is widely used in all critical care settings. Pulse oximeters may fail to provide valid pulse oximetry data in various situations that produce low signal-to-noise ratio. Motion artifact is a common cause of oximeter failure and loss of accuracy. This study compares the accuracy and data dropout rates of 3 current pulse oximeters during standardized motion in healthy volunteers. METHODS: Ten healthy volunteers were monitored by 3 different pulse oximeters: Nellcor N-200, Nellcor N-3000, and Masimo SET (prototype). Sensors were placed on digits 2, 3, and 4 of the test hand, which was strapped to a mechanical motion table. The opposite hand was used as a stationary control and was monitored with the same pulse oximeters and an arterial cannula. Arterial oxygen saturation rate was varied from 100% to 75% by changing the inspired oxygen concentration. While pulse oximetry was both constant and changing, the oximeter sensors were connected before and during motion. Oximeter errors and dropout rates were digitally recorded continuously during each experiment. RESULTS: If the oximeter was functioning before motion began, the following are the percentages of time when the instrument displayed a pulse oximetry value within 7% of control: N-200 = 76%, N-3000 = 87%, and Masimo = 99%. When the oximeter sensor was connected after the beginning of motion, the values were N-200 = 68%, N-3000 = 47%, and Masimo = 97%. If the alarm threshold was chosen as pulse oximetry < 90%, then the positive predictive values (true alarms/total alarms) are N-200 = 73%,

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N-3000 = 81%, and Masimo = 100%. In general, N-200 had the greatest pulse oximetry errors and N-3000 had the highest dropout rates. CONCLUSIONS: The mechanical motions used in this study significantly affected oximeter function, particularly when the sensors were connected during motion, which requires signal acquisition during motion. The error and dropout rate performance of the Masimo was superior to that of the other 2 instruments during all test conditions. Masimo uses a new paradigm for oximeter signal processing, which appears to represent a significant advance in low signal-to-noise performance.

The Effectiveness of Right Heart Catheterization in the Initial Care of Critically Ill Patients—AF Connors Jr, T Speroff, NV Dawson, C Thomas, FE Harrell Jr, D Wagner, et al. JAMA 1996;276(11):889.

OBJECTIVE: To examine the association between the use of right heart catheterization (RHC) during the first 24 hours of care in the intensive care unit (ICU) and subsequent survival, length of stay, intensity of care, and cost of care. DESIGN: Prospective cohort study. SETTING: Five U.S. teaching hospitals between 1989 and 1994. SUBJECTS: A total of 5,735 critically ill adult patients receiving care in an ICU for 1 of 9 prespecified disease categories. MAIN OUTCOME MEASURES: Survival time, cost of care, intensity of care, and length of stay in the ICU and hospital, determined from the clinical record and from the National Death Index. A propensity score for RHC was constructed using multivariable logistic regression. Case-matching and multivariable regression modeling techniques were used to estimate the association of RHC with specific outcomes after adjusting for treatment selection using the propensity score. Sensitivity analysis was used to estimate the potential effect of an unidentified or missing covariate on the results. RESULTS: By case-matching analysis, patients with RHC had an increased 30-day mortality (odds ratio, 1.24; 95% confidence interval, 1.03-1.49). The mean cost (25th, 50th, 75th percentiles) per hospital stay was $49,300 ($17,000, $30,500, $56,600) with RHC and $35,700 ($11,300, $20,600, $39,200) without RHC. Mean length of stay in the ICU was 14.8 (5, 9, 17) days with RHC and 13.0 (4, 7, 14) days without RHC. These findings were all confirmed by multivariable modeling techniques. Subgroup analysis did not reveal any patient group or site for which RHC was associated with improved outcomes. Patients with higher baseline probability of surviving 2 months had the highest relative risk of death following RHC. Sensitivity analysis suggested that a missing covariate would have to increase the risk of death 6-fold and the risk of RHC 6-fold for a true beneficial effect of RHC to be misrepresented as harmful. CONCLUSION: In this observational study of critically ill patients, after adjustment for treatment selection bias, RHC was associated with increased mortality and increased utilization of resources. The cause of this apparent lack of benefit is unclear. The results of this analysis should be confirmed in other observational studies. These findings justify reconsideration of a randomized controlled trial of RHC and may guide patient selection for such a study. *See the related editorial:* ***Is It Time to Pull the Pulmonary Artery Catheter?*** *JE Dalen, RC Bone. JAMA 1996;276(11):916-918.*

Do Children Who Experience Laryngospasm Have an Increased Risk of Upper Respiratory Tract Infection?—MS Schreiner, I O'Hara, DA Markakis, GD Politis. Anesthesiology 1996;85 (3):475.

BACKGROUND: Laryngospasm is the most frequently reported respiratory complication associated with upper respiratory infection and general anesthesia in retrospective studies, but prospective studies have failed to demonstrate any increase in risk. METHODS: A case-control study was performed to examine whether children with laryngospasm were more likely to have an upper respiratory infection on the day of surgery. The parents of all patients (n = 15,183) who were admitted through the day surgery unit were asked if their child had an active or recent (within 2 weeks of surgery) upper respiratory infection and were questioned about specific signs and symptoms to determine if the child met Tait and Knight's definition of an upper respiratory infection. Control subjects were randomly selected from patients whose surgery had occurred within 1 day of the laryngospasm event. RESULTS: Patients who developed laryngospasm (n = 123) were 2.05 times (95% confidence interval 1.21-3.45) more likely to have an active upper respiratory infection as defined by their parents than the 492 patients in the control group ($p \leq 0.01$). The development of laryngospasm was not related to Tait and Knight's definition for an upper respiratory infection or to recent upper respiratory infection. Children with laryngospasm were more likely to be younger (odds ratio = 0.92, 95% confidence interval 0.87-0.99), to be scheduled for airway surgery (odds ratio = 2.08, 95% confidence interval 1.21-3.59), and to have their anesthesia supervised by a less experienced anesthesiologist (odds ratio = 1.69, 95% confidence interval 1.04-2.7) than children in the control group. CONCLUSION: Laryngospasm was more likely to occur in children with an active upper respiratory infection, children who were younger, children who were undergoing airway surgery, and children whose anesthesia were supervised by less experienced anesthesiologists. Understanding the risk factors and the magnitude of the likely risk should help clinicians make the decision as to whether to anesthetize children with upper respiratory infection.

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What Is the Name of This Treatment (Disease, Abbreviation) Anyway? A Call for Terminology Standardization

I walked into a patient's room the other evening to administer an aerosol bronchodilator treatment to him. As I announced that I would like to give him a breathing treatment, he asked "Why does everyone call it something different?" This took me aback because I had no answer for him—ready or otherwise. It also got me thinking. I previously had thought that we did it only to ourselves. The proliferation of "alphabet soup" within the respiratory care community with its attendant confusion and miscommunication has been documented and lamented in the past.[1] After only a few minutes of thought, I was able to come up with a number of synonyms for different therapies.

A Therapy by Any Other Name?

Aerosol Therapy

Delivery of an aerosolized medication is variously termed aerosol therapy, hand-held nebulizer treatment, small volume nebulizer (SVN) treatment (or therapy), updraft nebulizer treatment, mist treatment, bronchodilator treatment, and probably others of which I am unaware.

Chest Physical Therapy

That part of chest physical therapy during which we percuss and vibrate the patient's thorax is variously known as CPT/PD, chest PT, chest physical therapy, clapping, cupping, pounding, and more.

Mechanical Ventilation

The device for or technique of mechanically assisted ventilation is referred to as mechanically assisted ventilation (MAV), continuous mechanical ventilation (CMV), mechanical ventilation, full ventilatory support (FVS), partial ventilatory support (PVS), ventilator, vent, respirator, or life-support system (In the newspaper or on television that sounds so impressive). However, I have yet to hear anyone call the device a blower, a term that seems reserved for superchargers for gasoline engines. The mechanical ventilation mode that allows spontaneous ventilation until minute volume drops below a preset level, at which point the ventilator begins to deliver mechanical breaths—is that AMV, MMV, or EMMV? Granted, the mechanism by which mandatory minute ventilation is accomplished *is* different among current mechanical ventilators. (For example, the Hamilton Veolar adjusts its pressure support level to achieve the desired MMV, or mandatory minute ventilation, level chosen; whereas, the Bear 5 and Bear 1000 generate mechanical breaths when the patient's measured minute volume falls below set levels.) And, what about weaning from the ventilator—T-tube, Briggs adapter, 'sink or swim,' even 'sprinting.' (IPPB, having fallen into disfavor after the halcyon early years of its abuse and overuse, seems not to have been subjected to the same imagination regarding associated terminology.) If we cannot agree on what to call something, how can we expect our patients to understand us when we talk to them?

Further, a recent report highlights the problem of lack of understanding of medical terminology among the lay public;[2] definitions for crackles included: "the part of a cereal which makes noises, noises made by breaking bubble wrapping, and noises made by laughing." Not one of those contacted associated crackles with breath sounds.

Confusion Prevails

Breath Sounds

What to do about this problem? Well, let's take a look back and see what history *hasn't* taught us. We need to go back to the 'Father' of auscultation of the chest to discover one source of confusion. Laënnec originally called discontinuous breath sounds râles,[3] but because he hesitated to use the term in front of patients and their families (as it had the connotation of the death rattle), he used rhonchus instead. Thus from nearly 2 centuries ago, we have what may be among the first examples of giving the same thing 2 different names.

Things pretty much 'perked along' for the next 150 years. In the 1960s, attention focused on problems related to confusing breath-sound terminology. Although râle had originally been introduced as a generic term for all adventitious sounds, its use was being narrowed to apply to discontinuous (explosive) sounds.[4] Robertson [5] suggested the use of the term crackles, perhaps eliminating Laënnec's original and now thoroughly confusing term. The confusion developed not in the original

writing but rather in the English translation, according to both Renzetti,[6] and Robertson[7] in an earlier semifictional paper. Hudson and colleagues[8] evaluated how well adjectives (fine to coarse, moist or dry) associated with râles contributed to their diagnostic usefulness; their conclusion was that there is no correlation between these adjectives and disease processes, and their use should be abandoned. Epler et al[9] bemoaned the decline in the art of auscultating the lungs for adventitious sounds. They blamed this on the fact that little attention has been paid to 4 essentials for progress—Number 3 among them being the "development of a uniform nomenclature." Forgacs[10] echoed this sentiment; he felt one important problem was that none of the terms used to describe breath sounds had yet been defined in the language of acoustics. In 1984, Loudon and Murphy endeavored to describe the state of the art of lung sounds.[11] They believed that there were major difficulties with nomenclature, highlighted by the fact that in the medical literature the same names are used to describe different sounds and the same sounds are described with different names. They advocated using the system proposed by the Ad Hoc Committee on Pulmonary Nomenclature of the American Thoracic Society some 7 years previously.[12] This system simplified the terminology to coarse or fine crackle to describe discontinuous sounds, wheeze to describe high-pitched continuous sounds, and rhonchus to describe low-pitched continuous sounds. That did not, however, put the matter to rest, as an anonymous editorial in Lancet in 1986 recommended that the terms crepitation, râle, *and* rhonchus be abandoned.[13]

Respiration & Gas Exchange

Perhaps discussion on terminology related to respiration and gas exchange has been going on longer than many such discussions. A glossary was initially developed by a committee of the International Union of Physiological Sciences and published in 1973.[14] It, unfortunately, contained some aberrancies, which included using both P_{AO_2}-P_{aO_2} or AaD_{O_2} as symbols for alveolar-arterial gas pressure difference and defining tachypnea as "increased breathing in comparison with breathing at rest (less exactly defined than and not to be confused with hyperventilation)." In 1985, Zander and Vaupel[15] recommended some changes because they believed that the definitions in the original glossary were now "either outdated or used in another sense." However, in their recommendations, they (to our confusion) try to distinguish between partial pressure and concentration of oxygen in blood by using -oxia to refer to partial pressure and -oxemia to refer to concentration (content). They also use 2 different terms to define the amount of O_2 transported within the arterial blood of the systemic circulation per unit time (oxygen supply and O_2 transport capacity; they use oxygen availability to describe oxygen transport to an organ). Elsewhere, they use $\dot{Q}_{O_2}$ to refer to oxygen consumption. ($\dot{Q}$, of course, is commonly used to refer to blood flow; $\dot{V}$, to gas flow.) Later, they opine that O_2 consumption is too general a term and as such should be avoided.

Oximetry was the specific topic of a 1985 symposium, the proceedings of which were published the next year.[16] The definitions and symbols proposed are not 'off the beaten path' at all: S_{O_2} for oxygen saturation measured manometrically or gasometrically, S_{pO_2} for oxygen saturation measured by pulse oximetry, and so on. Barker and colleagues,[17] publishing in 1989, utilized the symbols recommended by that 1985 conference. Yet that same year, the editor of IEEE Transactions on Biomedical Engineering invited 2 experts to comment on terminology regarding oxyhemoglobin saturation because reviewers had been pointing out that no consistent terminology existed at that time for pulse oximetry. In response to that request, Zijlstra and Oeseburg[18] defined oxygen saturation as the concentration of oxyhemoglobin divided by the concentration of hemoglobin that is able to combine with oxygen (typically, that which is measured by a pulse oximeter in vivo) and assigned the symbol S_{O_2}; oxyhemoglobin fraction (F_{HbO_2}) is oxyhemoglobin concentration divided by the total hemoglobin concentration (that which is typically measured by CO-oximeters in vitro). The principal point they espouse is that "physiological quantities should, if at all possible, be defined independent of the method used to measure them." They differentiate between use of the terms S_{pO_2} (inappropriate) and tcP_{O_2} (appropriate) by indicating that transcutaneous P_{O_2} is indeed different from arterial P_{O_2} and is, thus, a different quantity, whereas oxygen saturation is the same quantity regardless of how it is measured (assuming one agrees with the definition used).

In 1990, yet another group of voices was heard on this same topic. Wimberley et al[19] stated that the confusion in oxyhemoglobin saturation terminology is due to the fact that there are 2 conventions: the Pappenheimer convention promulgated in 1950, adopted by the American Physiological Society and generally used by physiologists and anesthesiologists, and the recommendations of the International Standards Organization (ISO), which have been adopted by the International Federation of Clinical Chemistry (IFCC) and the International Union of Pure and Applied Chemistry (IUPAC). They pointed out that a National Committee on Clinical Laboratory Standards (NCCLS) document[20] in draft form conforms closely to their recommendations. Zander and Mertzlufft[21] weighed in with their suggestions for definitions and symbols in the same issue of the Scandinavian Journal of Clinical Laboratory Investigation. They re-emphasized Zijlstra and Oeseburg's point that the quantities should be independent of the method used to measure them. The highlights of their recommendations include the fact that radicals or compounds containing oxygen should be referred to by "oxi", as carbon *monoxide*, whereas terms referring to molecular oxygen should be spelled as "oxy", as *oxymetry*. They also believe—because the number of symbols used for a given value should be kept as small as possible—Payne and Severinghaus' suggestions[16] should

not be followed because they recommended 6 different symbols for oxygen saturation. ISOTT (The International Society on Oxygen Transport to Tissue), founded in 1973, held a special round table discussion at its 1992 meeting to try to resolve what they termed the "Babel-like" confusion of terminology, definitions, and symbols. Zander and Mertzlufft reported on this discussion;[22] the general remarks on symbols were almost verbatim what they had suggested in their 1990 article.[21] The recommendations include: use of lower case letters for the quantities (such as p for pressure, s for saturation, or c for concentration), AaD_{O_2} for alveolar-arterial oxygen difference, $\dot{Q}_{O_2}$ as a synonym for $\dot{V}_{O_2}$, use of "oxia" (as normoxia) to refer to oxygen partial pressure and "oxemia" (as hypoxemia) to refer to oxygen concentration (requiring adjectives such as arterial, venous, or alveolar in front). Bizarrely enough, there was a separate publication of the proceedings of the entire 1992 ISOTT meeting.[23] Their recommendations were similar to those of the round table group. Within that same publication, a separate monograph by Severinghaus addresses solely the nomenclature of oxygen saturation,[24] the specifics of which are conspicuously absent from the ISOTT Proceedings.[23] Severinghaus endorses the terminology advocated by the NCCLS,[20] the European Committee for Clinical and Laboratory Standards (ECCLS),[25] the International Federation of Clinical Chemistry,[26] Zijlstra et al,[18] and Wimberley et al.[19] This consensus defines oxygen saturation as the ratio of oxyhemoglobin concentration to the sum of deoxyhemoglobin concentration and oxyhemoglobin concentration (such as that measured by pulse oximeters) and oxyhemoglobin fraction as the ratio of oxyhemoglobin concentration to total hemoglobin concentration (such as that measured by CO-oximeters).

Other Disciplines

The controversy regarding definitions, terminology, and symbols is not limited to respiratory physiology. Bone has led the charge focusing on terms used for sepsis and multisystem organ failure, first in 2 editorials published 5 months apart[27,28] and then in reporting the results of an ACCP/SCCM consensus conference.[29] There have been papers offering opinions on terminology used in cardiology,[30] that relating to the study of ischemia and reperfusion,[31] and that relating to patients with severe alterations in consciousness;[32] terminology related to capnography has been reviewed.[33]

"Everybody talks ... but no one..."

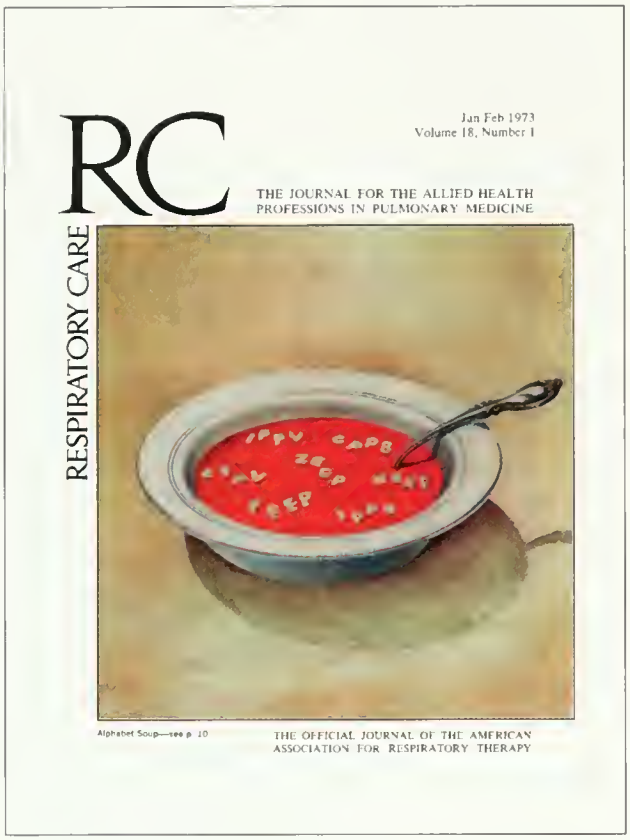
Under the heading of "Everybody talks about terminology but no one does anything about it," several surveys have been published over more than a decade on the use of breath sound terminology. Early on, authors simply reported what terminology had been published in case reports in the literature.[34,35] Later, they reported on the descriptions of pre-recorded breath sounds by both physicians and respiratory care practitioners.[36-39]

Perhaps some breathed a sigh of relief when, in 1993, the College of American Pathologists released the latest version of SNOMED International (Systematized Nomenclature of Medicine), a "structured, modular, multipurpose healthcare nomenclature and taxonomy for the categorization of concepts related to human and veterinary medicine."[40] Given the complexity and relative completeness of this system, one would think this had, at last, solved the problem of confusing terminology. Talbot and Mills[41] advocated its use to facilitate quality assurance, cost containment, and documentation of practice guidelines in veterinary medicine. Their major point was that none of these activities can proceed well without computer-based medical systems, which rely on a standard system of nomenclature. In one of their examples, they show how the "anterior leaflet of the mitral valve" would be classified. Shortly thereafter, however, Habel took exception to their terms, pointing out that "septal cusp of the left atrioventricular valve" is the preferred terminology in veterinary medicine.[42]

In 1988, the Canadian Society for Respiratory Therapy Examinations Advisory Committee, aware of the proliferation of terms and symbols, took a stand on what terms would be used in the CSRT Examinations.[43] Although this was a laudable effort, it probably did little to help the practitioner who was trying to make sense of the terms in preparing for the exam, especially if the practitioner did not have access to the nomenclature document.

For a picture (literally) of this problem, one need only look at Figure 1, the cover of the 1973 January-February issue of RESPIRATORY CARE, to find a bowl of alphabet soup. Two editorials in that issue worth reviewing are those by Petty[44] ("Alphabet Soup") and Kittredge[45] ("Guise and Dolls"). Confusion was present even then when Kittredge pointed out that "the term CPAP has become obsolete and Gregory prefers that it not be used."[46] Unfortunately, in the intervening 20 years it seems not much has changed. People continue to use their own favorites. There is occasionally a physician, for example, who does not like the term crackle, the 1977 report from the ACCP-ATS notwithstanding. At least we have gotten away from adjectives in front of râle (or crackle, or whatever term *is* used), such as sibilant, musical, crepitant, subcrepitant, sonorous, and flatulent (just wanted to be sure you were still paying attention!). The latest entry in this seemingly unending dialogue was made by Chatburn[47] in 1994 in his response to a letter by Blanch and Desautels[48] criticizing his proposed and apparently widely accepted mechanical ventilator classification system.

Those of us in education could (if we could agree among ourselves) start the proverbial ball rolling by inculcating a love for clarity in our students and by teaching consistent terms and symbols. The instructors in the educational program with which I am associated seem to have narrowed the terms for breath sounds down to crackles or râles for discontinuous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RESPIRATORY CARE
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Alphabet Soup—see p. 10
THE OFFICIAL JOURNAL OF THE AMERICAN ASSOCIATION FOR RESPIRATORY THERAPY

Fig. 1. The cover of a 1973 issue of RESPIRATORY CARE depicting 'alphabet soup.'

sounds and wheezes and rhonchi for continuous sounds (with rhonchi generally referring to those sounds of lower pitch). But that doesn't help us in talking with our patients. Why can't we all use the same terms, at least to start? The time has clearly come, more than 22 years after the "Alphabet Soup" and "Guise and Dolls" editorials and 20 years after the publication of the ACCP-ATS report, for a consensus conference on terminology. In medicine, in which the presence or absence of a single letter can change a definition completely (pyogenic vs pyrogenic, for example), clarity of communication is of utmost importance. Many problems among people also can be traced to a breakdown in communication. The American Association for Respiratory Care would do respiratory care, pulmonary and critical care medicine, and most importantly, patients, a great service by sponsoring and organizing such a conference—bringing players from each of the subdisciplines 'to the table' to decide how we should talk and write.

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Another Corner on the Market?

In this issue of the Journal, we introduce Graphics Corner—a teaching feature devoted to presentation, analysis, interpretation, and discussion of waveforms and traces generated by monitoring components of mechanical ventilators and standalone monitors of all types. Jon Nilsestuen, Ken Hargett, and Robert Harwood head up this effort as Section Editors.

An overview of ventilator graphics "Managing the Patient-Ventilator System Using Graphic Analysis" appears this month, with case studies to follow in December, February, and beyond. So, have you seen any good shows lately—a classic presentation of a common problem, a depiction that had your staff wondering whether the problem was patient or monitor related or, perhaps, a monitor looking for a pathology? Contact the Section Editors and 'go for' bringing it to publication. Do you need answers to questions or have 'wonder abouts' regarding some puzzling observation that you have made clinically? Contact the Section Editors and discuss those questions with them. They not only will work with you toward answers but may also use those questions to develop features that will help others, too. Do you want to fully utilize all the 'bells and whistles' on that new piece of equipment, but don't quite know what is real and what is not? Contact the Section Editors and talk it over with them.

The 'Corners'—Test Your Radiologic Skill, PFT Corner, Blood Gas Corner, Kittredge's Corner, Cardiopulmonary Interactions, and now Graphics Corner—offer unique opportunities for clinicians, program coordinators, instructors, and students to make the most of learning situations that present themselves every day. Each Corner focuses on a clinical problem or presentation, 'paints a picture,' raises cogent questions, methodically answers those questions, broadens the focus with discussion, and provides some related references.

Use Corners to broaden your knowledge and understanding and increase your awareness of clinical conundrums. Use the preparation of a Corner as a way to 'break into print,' a way to become 'published.'

Development of a Corner (with help from instructors) is an excellent mechanism for senior, respiratory care students to pull together some of the many facets of their clinical rotation. The format is spelled out, the size is manageable, and the Journal's editors and Section Editors stand ready to help.

Pat Brougher
Editor
Dallas, Texas

RESPIRATORY CARE

Special Issue

Emerging Health Care Delivery Models and Respiratory Care

January 1997

Manual Volume-Controlled Ventilation in Preterm Neonates Compared to Ventilation via Self-Inflating Resuscitator

Gamal F Monem MD, Niranjan Kissoon MD, Suzanne Murphy PhD, Kathryn Blake PharmD, Arthur Vaughn MD, Chris Taylor RRT, and James Kirk DO

BACKGROUND: Although studies suggest that manual volume-controlled ventilation (VCR) may have advantages over manual ventilation provided with a self-inflating resuscitator (SIR), this has not been studied in preterm neonates. In this study, we compared manual VCR to manual SIR. METHODS: Experienced neonatal nurses ventilated 9 intubated preterm neonates in a tertiary care neonatal unit for a period of 5 minutes using the SIR and VCR in random sequence. The VCR was initially set at a tidal volume of 10 mL/kg and adjusted after 30 seconds if deemed necessary for adequate chest expansion. Heart rate, respiratory rate, oxygen saturation, mean airway pressure, and end-tidal carbon dioxide were measured at 0, 2.5, 5, and 15 minutes. Arterial blood samples were obtained at 0 and 5 minutes of ventilation and analyzed for pH, P_{aCO_2}, and P_{aO_2}. Pressure tracings were inspected to determine highest (PIP_{max}) and lowest peak inspiratory (PIP_{min}) pressures. $PIP_{max} - PIP_{min}$ was used as a measure of pressure variability. RESULTS: Appropriate ventilation was achieved with both resuscitators. No significant differences ($p > 0.05$) between baseline and post-trial measurements were seen in any of the measured variables for either device. However, ventilation with the VCR was achieved at significantly lower PIP_{max} (mean ± SD) (30 ± 9 vs 39 ± 7 torr, 4.0 ± 1.2 vs 5.2 ± 0.93 kPa, $p = 0.03$) and with less variability in PIP_{diff} (14 ± 4 vs 24 ± 7 torr, 1.9 ± 0.53 vs 3.2 ± 0.93 kPa, $p = 0.001$). CONCLUSION: In preterm neonates, manual ventilation using the VCR allows ventilation comparable to that supplied with the SIR but at lower PIP_{max} and with less pressure variability. [Respir Care 1996;41(12):1083-1089]

Introduction

Premature neonates, particularly those with a birthweight of < 2,000 grams, are at higher risk for respiratory distress and failure than full-term neonates and older infants.[1] These neonates are more vulnerable to barotrauma due to their small lung volume, decreased total lung compliance, and increased chest-wall compliance than older neonates and infants.[2]

Manual ventilation of preterm neonates has been limited to the use of self-inflating and anesthesia bags. Anesthesia bags allow the operator to control the system leak level (so-called pop-off) and, thus, system pressure.[3] However, effective use of an anesthesia bag requires an experienced operator, and the possibility of delivering high inflation pressure always exists. In addition, inadequate ventilation due to increased rebreathing as fresh gas flow declines is a recognized complication of these systems.[3-5] These disadvantages make the systems less than ideal for use in ventilation of premature neonates.

Self-inflating resuscitators (SIRs) are frequently used for

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ventilation because of their simplicity.[6] However, the extreme variability of pressures necessary to activate the pressure relief mechanism could be hazardous to neonates, particularly those < 2,000 grams, who are at highest risk of barotrauma and intraventricular hemorrhage.[7] In addition, the tendency toward hyperventilation with excessive pressure, limitation in maximum fraction of delivered oxygen, and difficulty in maintaining uniform positive end-expiratory pressures are factors that may be of clinical importance in the preterm neonate.[6-9]

Increased awareness of the possible adverse consequences of excessive (and variable) pressure and consequent excessive volume (ie, volutrauma) associated with manual ventilation with anesthesia bags and SIRs has stimulated renewed interest in volume-controlled ventilation, thought to be a promising mode of ventilation for neonates.[3,4] We had previously evaluated the $NeoV_{O_2}R$* (Fig. 1) in full-term neonates and infants and found less variation in peak airway pressure (PIP) and less hyperventilation at comparable mean airway pressure ($\bar{P}_{aw}$), as compared to the SIR.[10] However, this device has not been tested in preterm neonates, a group likely to derive the greatest benefit.

Fig. 1. The neonatal volume-controlled resuscitator ($NeoV_{O_2}R$) evaluated in the study.

Our hypotheses entailed a comparison of cardiorespiratory and airway pressure variables for both resuscitators. Our primary hypothesis was that the volume-controlled resuscitator (VCR) would provide more physiologic ventilation than the SIR as reflected by minimal variation in steady state P_{aCO_2}, end-tidal CO_2 (P_{etCO_2}), pH, P_{aO_2}, oxyhemoglobin saturation measured by pulse oximetry (S_{pO_2}), and $\bar{P}_{aw}$ in preterm neonates. Our secondary hypothesis was that there would be no significant differences in heart rate, respiratory rate, and mean arterial blood pressure measured during SIR versus VCR.

Materials & Methods

The Volume-Controlled Resuscitator

The $NeoV_{O_2}R$ (Fig. 2) consists of a hand-held bulb connected to an inflatable bellows that is situated within a graduated cylinder. This cylinder is attached to the patient circuit, which is vented to the exhalation valve. The desired volume of gas is obtained by releasing the lock nut and moving the adjustable piston inside the graduated cylinder. The delivered tidal volume (V_T) is adjustable but is limited to the preset maximum, regardless of how vigorously the hand-held bulb is squeezed. The device has been fully described in previous studies.[10-12]

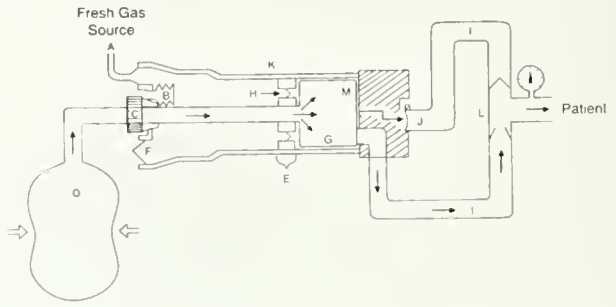

Fig. 2. Schema of the $NeoV_{O_2}R$: A = fresh gas source; B = pressure-equalizing bellows; C = lock nut; D = hand bulb; E = adjustable piston inside of graduated cylinder; F = 1-way outflow valve to atmosphere; G = bellows; H = 1-way valve; I = circuit; J = exhalation valve; K = graduated cylinder; L = 1-way valves to prevent rebreathing; M = pressure chamber.

Study Protocol

The study was conducted in the Neonatal Intensive Care Unit of Wolfson Children's Hospital between May 1992 and May 1993. A convenience sample of preterm neonates who met the inclusion criteria were enrolled in the study, which was approved by the Institutional Review Board of the Wolfson Children's Hospital. All patients were endotracheally intubated and receiving continuous positive pressure ventilation. Patients with prematurity and respiratory distress syndrome were included in the trial only when clinically stable and following written parental informed consent (Table 1). Neonates with congenital hypoplastic lungs, congenital diaphragmatic hernia, air leak syndromes (pulmonary interstitial emphysema or pneumothorax), and congenital cyanotic heart disease were excluded. Convalescent infants were chosen (as opposed to acutely ill neonates who may be more prone to adverse sequelae of improper ventilation) in order to explore safety and feasibility issues prior to advocating more widespread use of the VCR.

To determine the effect of ventilation only on cardiorespiratory variables, patients were not studied immediately prior to tracheal suctioning or lavage because these maneuvers may in themselves alter the study variables. Following baseline measurement, subjects were ventilated manually for a period of 5 minutes by nurses with an average of 5 years of neonatal intensive care experience, using the VCR and SIR in random sequence. Following ventilation with either device, the patient was returned to mechanical ventilation for at least 20 minutes to achieve steady state before use of the alternate resus-

*Suppliers of commercial products are identified in the Product Sources Section at the end of the text.

Table 1. Demographic Data for the 9 Study Infants with Respiratory Distress Syndrome (RDS) and/or Bronchopulmonary Dysplasia (BPD)

Patient	Trials	Ventilator Days	Weight (g)	Ventilation Rate (breaths/min)	Gender	Peak Pressure (cm H_2O)	PEEP (cm H_2O)	Intra-Arterial Gases?	Diagnosis
1	5	21	1118-1198	5-20	F	18-19	4	Yes	RDS
2	2	113	2037-2115	28	F	38	5	No	BPD-RDS
3	2	36	526	10	M	21	5	No	BPD-RDS
4	2	17	1900-2030	7-25	M	20-22	5	No	RDS
5	2	15	853	15	F	22	5	No	RDS
6	2	17	520-532	37	F	22	4	No	BPD
7	2	3	1532-1555	55-60	F	30-32	4	No	RDS
8	3	23	1144-1255	8-13	M	18-20	3-5	No	BPD-RDS
9	4	46	626-704	6-7	M	16	3	No	BPD-RDS
Mean (SD)		28.7 (27.8)		21.5 (5.9)		21.5 (5.9)	4.1 (0.8)		

citator. The initial V_T of the VCR was set at 10 mL/kg, and the pressure release at 40 cm H_2O. Nurses were blinded to P_{etCO_2} and ventilatory pressure values. If the nurse judged chest expansion to be inadequate, the V_T was adjusted after 30 seconds. During manual ventilation with the SIR, the nurse was also instructed to ensure adequate chest expansion.

A single trial consisted of ventilation with each device and measurement of variables, within 1 to 3 hours of each other. One neonate had 5 trials, one had 4, one had 3, and six had 2. Trials were conducted on different days (1 trial/day); the same nurse did not necessarily conduct the repeat trials on subsequent days. Infants were selected for repeated trials if they remained intubated and clinically stable.

Monitoring

At baseline and at 2.5, 5, and 15 minutes from the beginning of manual ventilation, we recorded P_{aCO_2}, P_{etCO_2}, pH, P_{aO_2}, S_{pO_2}, and $\overline{P}_{aw}$. Arterial blood samples were obtained at baseline and at the end of 5 minutes of ventilation and analyzed within 5 minutes using the same calibrated analyzer. Continuous electrocardiographic monitoring was performed and expired carbon dioxide was monitored with an end-tidal capnograph. PIPs, $\overline{P}_{aw}$s, and respiratory rate were monitored, and oxygenation was assessed with a pulse oximeter. The blood pressure of patients with an intra-arterial catheter was continuously monitored. Patients who did not have intra-arterial catheters were monitored by cuff pressure.

During the study, time-pressure tracings were recorded in 12 of 24 trials to determine the highest and lowest peak inspiratory pressure (PIP_{max} and PIP_{min}). Peak inspiratory pressure differences ($PIP_{max} - PIP_{min} = PIP_{diff}$) were used as a measure of pressure variability generated by each resuscitator during ventilation.

Analysis of Data

Data were collected for a total of 24 trials. Friedman's 2-way ANOVA was used to examine differences between time periods for heart and respiratory rate, $\overline{P}_{aw}$, P_{aO_2}, P_{aCO_2}, pH, S_{pO_2}, P_{etCO_2}, and PIPs for both the SIR and VCR and to test for differences between the two devices. The significance level was set at $p < 0.01$. The Mann-Whitney U test was used to examine the differences between PIP_{max}, PIP_{min}, and PIP_{diff}. Results of each of the monitored variables are expressed as mean and standard deviation (SD), with error bars in graphs representing standard deviation.

Results

The 9 preterm neonates, 4 boys and 5 girls, were studied for a total of 24 trials. The mean (SD) weight during the study was 1,124 (516) g with a range of 520-2,035 g. Ages ranged from 11 to 107 days. All infants had a clinical and radiologic diagnoses of respiratory distress syndrome or bronchopulmonary dysplasia (Table 1). The mean values of each of the variables for the VCR and SIR trials are provided in Tables 2 and 3. No statistically significant differences were found between the two resuscitators with respect to respiratory rate, P_{etCO_2}, S_{pO_2}, $\overline{P}_{aw}$ (Fig. 3), P_{aO_2}, P_{aCO_2}, pH, or HCO_3^- (Fig. 4). Further, no statistically significant differences were found for these variables between time periods for either resuscitator, the mean baseline heart rate was the same for both resuscitator groups, and no statistically significant differences were seen in the mean heart rate between time periods for either resuscitator.

Table 4 displays the pressure values for the VCR and SIR. Ventilation with the VCR was achieved at a significantly lower value PIP_{max} and with less variability in PIP_{diff} when compared to self-inflating resuscitator. The mean values for PIP_{max}, PIP_{min}, and PIP_{diff} are displayed in Figure 5. An example of a strip chart recording from one neonate is shown in Figure 6. As can be seen, the wide variability in PIPs are due almost entirely to the marked variations in PIP_{max}.

No neonate suffered complications related to the use of either device. More specifically, no neonate suffered periods of desaturation ($S_{pO_2} < 90\%$), air leak syndrome, or failure to return to baseline cardiopulmonary status within 5 minutes after the trial period with either device. In only one trial was

Table 2. Study Variables for the Trials of Ventilation by Volume-Controlled (VCR) and Self-Inflating Resuscitators (SIR)

Variable	Measurement Point							
	Baseline		2.5 Minutes		5.0 Minutes		15.0 Minutes	
	VCR	SIR	VCR	SIR	VCR	SIR	VCR	SIR
Heart Rate	160 (15)*	160 (14)	163 (18)	163 (16)	162 (15)	165 (15)	161 (14)	161 (13)
Respiratory Rate	55 (17)	53 (14)	52 (9)	53 (16)	54 (10)	53 (16)	53 (11)	53 (11)
$P_{et}CO_2$								
torr	37 (8)	38 (7)	38 (10)	39 (12)	35 (8)	39 (12)	36 (7)	38 (7)
kPa	4.92 (1.06)	5.05 (0.93)	5.03 (1.33)	5.19 (1.60)	4.66 (1.06)	5.19 (1.60)	4.79 (0.93)	5.05 (0.93)
S_{pO_2} (%)	91.7 (3.6)	91.3 (3.0)	91.5 (3.8)	91.3 (4.4)	91.6 (4.1)	92.1 (3.9)	91.8 (2.9)	91.8 (3.5)
$\bar{P}_{aw}$								
cm H_2O	6.3 (3.0)	6.7 (3.5)	6.7 (3.5)	7.0 (3.4)	6.9 (3.2)	7.1 (3.9)	6.3 (2.6)	6.4 (3.1)
kPa	0.62 (0.29)	0.66 (0.34)	0.66 (0.34)	0.69 (0.33)	0.68 (0.31)	0.70 (0.38)	0.62 (0.25)	0.63 (0.30)

*All values are mean (SD); P_{etCO_2} = end-tidal CO_2 tension; S_{pO_2} = hemoglobin saturation by pulse oximetry; $\bar{P}_{aw}$ = airway pressure.

Table 3. Blood Gas Values for Arterial Samples Drawn at Baseline and at 5 Minutes of Manual Ventilation by Volume-Controlled (VCR) and Self-Inflating Resuscitator (SIR)

Variable	Baseline		5 Minutes	
	VCR	SIR	VCR	SIR
P_{aO_2}				
torr	50.6 (11.4)*	52.6 (12.9)	54.0 (14.2)	55.5 (18.4)
kPA	6.72 (1.52)	7.00 (1.72)	7.18 (1.89)	7.38 (2.45)
P_{aCO_2}				
torr	48.8 (6.6)	48.3 (7.4)	48.6 (7.8)	50.0 (14.8)
kPA	6.50 (0.88)	6.42 (0.98)	6.46 (1.04)	6.65 (1.97)
pH	7.33 (0.04)	7.33 (0.04)	7.34 (0.04)	7.34 (0.08)
HCO_3 (mmol/L)	20.7 (12.5)	20.9 (12.6)	20.7 (12.4)	20.8 (12.5)

*All values are mean (SD).

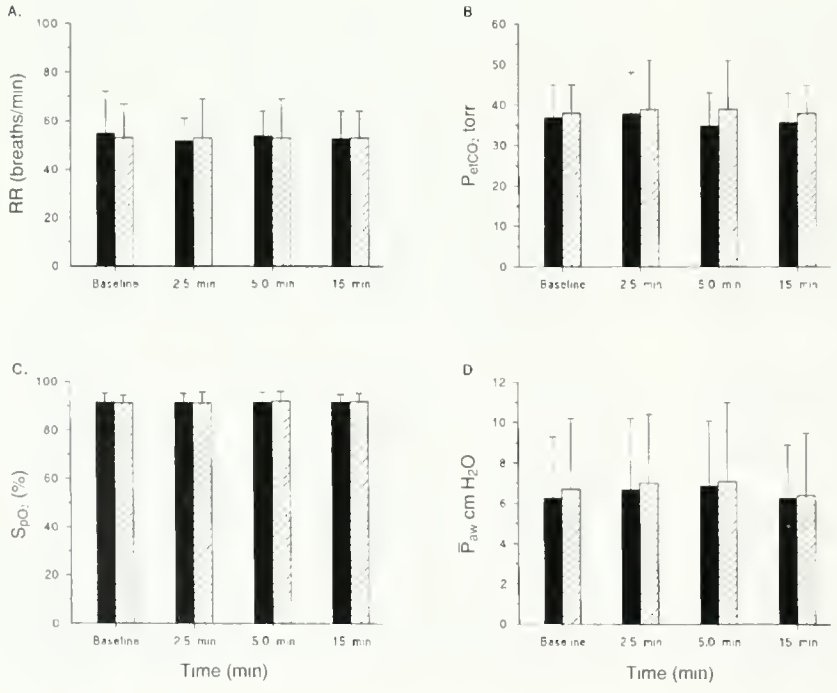

Fig. 3. Comparison of study variables for the volume-controlled and self-inflating resuscitator. RR = respiratory rate, P_{etCO_2} = end-tidal carbon dioxide tension, S_{pO_2} = oxygen saturation by pulse oximeter, $\bar{P}_{aw}$ = mean airway pressure.

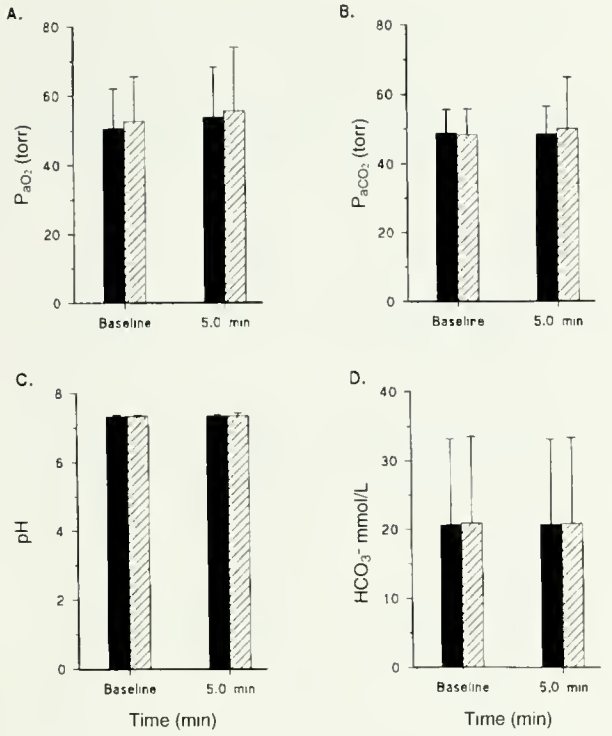

Fig. 4. Comparison of study variables for the volume-controlled and self-inflating resuscitators. P_{aO_2} = tension of oxygen in arterial blood (torr), P_{aCO_2} = tension of carbon dioxide in arterial blood (torr), HCO_3^- = bicarbonate (mmol/L).

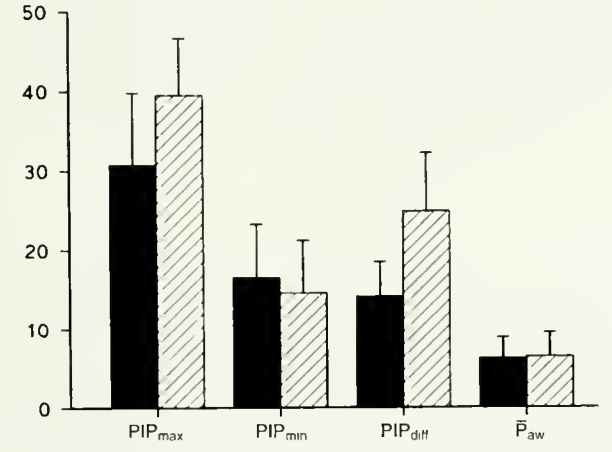

Fig. 5. Mean values for maximum inflation pressures (PIP_{max}), lowest inflation pressures (PIP_{min}), and their difference (PIP_{diff}), and mean airway pressures ($\bar{P}_{aw}$).

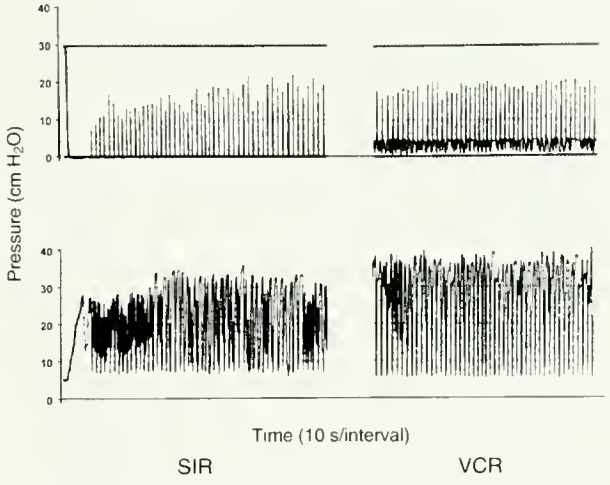

Fig. 6. Strip chart recording during ventilation of one infant with the self-inflating resuscitator (SIR) and the volume-controlled resuscitator (VCR).

the V_T increased from 10 to 12 mL/kg by the nurse because she judged chest expansion to be inadequate.

Discussion

It is generally acknowledged that appropriate, safe manual ventilation of the premature neonate may be difficult, especially in the hands of unskilled personnel and in anxiety provoking situations such as occur in delivery rooms or emergency departments and during acute deterioration. Available SIRs have several limitations that may render achievement of optimal ventilation difficult.[6-9] Premature neonates have smaller lung volumes, higher compliance (secondary to more pliable chest wall), lower or decreased functional residual capacity, and higher closing volumes than do full-term neonates or infants.[2] Premature neonates are also at a disadvantage because of increased oxygen consumption and metabolic demands of breathing.[13,14] These factors coupled with the anatomic peculiarities of the premature neonatal airways, make these infants more susceptible to the complications of manual ventilation than are other groups.

SIRs have been criticized for their inability to deliver accurate, constant V_Ts, and their pressure variability.[6,7,15,16] Kanter found wide variations in the mean V_T delivered and a tendency to hyperventilate with excessive pressures when the

Table 4. Comparison of Minimum and Maximum Peak Inspiratory Pressures (PIP_{min} & PIP_{max}) and Pressure Variability ($PIP_{min} - PIP_{max}$) for the Volume-Controlled (VCR) and Self-Inflating Resuscitator (SIR)

Pressure Unit	PIP_{min}		PIP_{max}		PIP_{diff}	
	VCR	SIR	VCR	SIR	VCR	SIR
cm H_2O	15.5 (6.7)	15.3 (6.3)	29.3 (9.2)	40.3 (6.7)	13.8 (4.4)	24.9 (6.7)
kPa	1.52 (0.65)	1.50 (0.62)	2.87 (0.90)	3.94 (0.66)	1.36 (0.43)	2.44 (0.66)

pediatric SIR was used by trained personnel.[6] Finer et al[7] compared the performance of three commonly used SIRs and found that pressure-limit valves were activated through a broad range of pressures that often exceeded the manufacturer's specification. Studies have shown that SIRs, even with reservoir attachments, high oxygen flow, and other various modifications, are unable to deliver an F_{O_2} of 1.0.[17-19] Although this may be less of a problem in neonates, it may limit the effectiveness of SIRs in those premature neonates who are at high risk of hypoxia due to lung disease and increased oxygen consumption.

The VCR studied can deliver an F_{O_2} of 1.0 consistently because there is no entrainment of room air. This capability is due to the pressure equalizing bellows (Fig. 2), which allows a constant rate of refilling of the bulb over a wide range of fresh gas flows. Constant refilling permits an unchanged level of ventilation (V_T and rate) even if the fresh gas flow is moderately decreased. This may be especially advantageous in neonates because decreasing the rate of ventilation to accommodate low flows may be hazardous during ventilation of neonates who inherently have higher respiratory rates.[17] A potential disadvantage of the VCR may be the difficulty encountered in changing the V_T in a crisis situation. However, this was not a major concern during our study, which was conducted in stable neonates by experienced nurses. Further studies in delivery rooms and during resuscitation are needed to address this issue.

In this study, a comparison of post-trial arterial blood gas values revealed no significant differences in pH, P_{aCO_2}, or P_{O_2}. In addition, the post-trial P_{etCO_2} values for both devices showed no significant differences. Our previous studies in cats and in full-term neonates and children demonstrated that the use of the VCR resulted in less hyperventilation than did use of the SIR.[10,11,20] Post-ventilation respiratory alkalosis was not seen after any of our present trials, whereas in the previously reported trials 16% of infants ventilated with the VCR and 56% of infants ventilated with the SIR were alkalotic after the ventilation trial.[10] This could be partially explained by the fact that all our patients in the present study were ventilated by experienced nurses, whereas the previous studies were done using personnel with varying levels of skill. This finding suggests that, in preterm neonates, use of the VCR results in similar ventilation as compared to the SIR when used by skilled personnel. Unfortunately, these operators may not represent the majority of personnel who are required to perform manual ventilation in various clinical situations. Another explanation is that our patients have generally the same or uniform pathologic process of acute lung disease of prematurity as compared to the previous studies in which animals with normal lungs and infants with varying pulmonary pathophysiologic derangements were studied.

Analysis of the strip chart recordings (Fig. 6) shows significant variations in PIP_{max} and PIP_{diff} between the SIR and the VCR. These variations may be attributable to the variability in pressure-relief-valve pressures or to the variable compression of the resuscitation bag even in skilled hands. Variable compression of the resuscitation bag is even more likely to occur under stress and in panic situations, such as resuscitation in the delivery room, operating room, or emergency department. The VCR shows fewer fluctuations in PIP_{max} and PIP_{diff}, which makes it more suitable for resuscitation of premature infants because large variations in inspiratory pressure are associated with blood pressure fluctuations that may precede intraventricular hemorrhage.[21] In premature neonates, high $\bar{P}_{aw}$ has also been implicated in the etiology of pulmonary barotrauma and the development of bronchopulmonary dysplasia.[22-24] In our study the $\bar{P}_{aw}$ and PIP_{min} values between trials were not statistically different. However, because our trials were done in stable patients, in a non-stressed intensive care environment and by experienced neonatal nurses, our findings may underestimate the actual variability in $\bar{P}_{aw}$. We did not measure exhaled V_Ts, but one might conjecture that even greater variability in delivered V_Ts could be associated with the pressure variability.

The minimal pressure fluctuations with the VCR in the intensive care environment makes it suitable for pre-oxygenation prior to routine tracheal toilet. It may also be suitable in situations in which manual ventilation is be required for extended periods such as during intrahospital transport and radiographic studies. The small variations in ventilatory pressures seen with the VCR despite a preset V_T is not surprising. It may occur as a result of incomplete squeezing of the hand bulb resulting in delivery of submaximal V_Ts. It can also occur if a decrease in gas flow is substantial and uncompensated for by the pressure equalizing bellows. Additionally, none of our patients were paralyzed during the trials; as a result, cough and agitation may have contributed to the observed pressure variations.

In Conclusion

The data from this study suggest that similar ventilation can be achieved with the volume-controlled resuscitator as compared to the self-inflating resuscitator, with less variation in peak inspiratory pressure during manual ventilation of premature neonates. This device shows promise in this group of patients and warrants further investigation in other disease states and clinical settings. Although less pressure variation may render the volume-controlled resuscitator superior in crisis situations, this needs to be proven.

PRODUCT SOURCES

Manual Resuscitators:

Volume-controlled—NeoV_{O_2}R, Neo-Med London, Ontario, Canada
Self-inflating—Laerdal, Stavenger, Norway
Infant Ventilator—Bear Cub 2001, Bear Medical, St Louis MO

Analyzers & Monitors:

Radiometer ABL500 analyzer, Radiometer Inc, Copenhagen, Denmark
Cardiorespiratory monitor—Hewlett Packard Model #66, Palo Alto CA

Capnometry monitor—Hewlett Packard M1016A, Palo Alto CA
Ventilator function—P-7 Bird scanner, Bird Medical Products, Palm Springs CA
Pulse oximeter 4500 plus 3, In Vivo Research Inc, Winter Park FL
Intra-arterial blood pressure—Neocath 1000, Shiley, Kansas City MO
Arterial blood pressure monitor—1846 Dynamap, Criticon, Tampa FL

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Foreword for a Special Article

Reporting Accuracy Data

Many device evaluation studies are found in this and other journals. A common way of presenting the results is to use the limits-of-agreement approach described by Bland and Altman,[1] wherein the upper and lower limits of expected differences in measurements are expressed as the mean difference (or bias) ± 2 standard deviations. But, as Bland and Altman explain, this is just a point estimate and varies as a function of the number of repeated measurements (ie, the sample size). In fact, it has been suggested[2] that this method not be used with samples of < 100, although it is often impractical to perform an experiment of such size.

Here is the problem and a proposed solution: Given a set of repeated measurements of the same quantity, we want to determine the range of values that we might expect to observe with a specified degree of confidence. If the true mean (μ) and standard deviation (σ) of an infinite number of repeated measurements were known, then a 2-σ (ie, approximately 2 standard-deviation) tolerance interval (TI) can be expressed as $TI = \mu \pm 1.96\sigma$. This interval includes exactly 95% of the measurements, and therefore we can say this with 100% confidence. Of course, μ and σ are unknowable; therefore, we must substitute the appropriate point estimates $\bar{x}$ and s (the sample mean and standard deviation). Because of the random error involved in estimating the population mean and standard deviation, the proportion of the population of measured values covered by the tolerance interval is not exact. As a result, the confidence level must be calculated based on the uncertainty of the point estimates of the population parameters. The tolerance interval is expressed as:[3-5]

$$TI = \bar{x} \pm k_1 s,$$

where $\bar{x}$ is the sample mean value and s is the sample standard deviation from an experiment consisting of repeated measurements of a known quantity. The factor k_1 is determined so that one can assert with the desired confidence that the given limits contain at least 95% of the measurements.[4,5] The value of k_1 is selected by determining the confidence level and the sample size n (Table 1[6]).

Table. 1. Factors for Determining 2-σ, or 2-Standard-Deviation, Error Intervals (ie, Intervals Containing 95% of Observed Measurements); n = Sample Size. (Condensed from the Table of Odeh and Owen[6])

	Confidence Level			Confidence Level	
	95%	99%		95%	99%
n	k_1	k_1	n	k_1	k_1
2	36.52	182.72	52	2.37	2.56
4	6.34	11.12	54	2.36	2.55
6	4.42	6.37	56	2.35	2.54
8	3.75	4.97	58	2.34	2.52
10	3.39	4.29	60	2.33	2.51
12	3.18	3.90	65	2.32	2.48
14	3.02	3.61	70	2.30	2.46
16	2.91	3.44	75	2.29	2.46
18	2.83	3.30	80	2.27	2.42
20	2.76	3.18	85	2.26	2.40
22	2.71	3.09	90	2.25	2.38
24	2.66	3.02	100	2.23	2.36
26	2.62	2.95	110	2.22	2.34
28	2.59	2.90	120	2.21	2.32
30	2.56	2.85	130	2.20	2.30
32	2.53	2.81	140	2.19	2.28
34	2.51	2.77	150	2.18	2.27
36	2.48	2.74	160	2.17	2.26
38	2.47	2.71	170	2.16	2.25
40	2.45	2.68	180	2.15	2.24
42	2.43	2.66	200	2.14	2.22
44	2.42	2.64	500	2.07	2.12
46	2.41	2.62	1000	2.04	2.07
48	2.39	2.60	infinity	1.96	1.96
50	2.38	2.58			

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Given that we want the highest confidence in our estimate and given that we often assume 100% confidence in the limited data supplied by manufacturers, we should probably select a value of k_1 at the 99% confidence level. We interpret this to mean that if 100 experiments are conducted and 100 tolerance intervals calculated, then in 99 of 100 experiments, we would observe 95% of the data from the experiment to lie within the associated tolerance intervals.

If we need to describe an experiment comparing repeated measurements of a known value on a single machine, we can express the device's inaccuracy interval as the bias $\pm k_1$ standard deviations of the differences. An agreement interval for comparing two devices can be expressed the same way, with bias being the mean difference between measurements of the same quantity and the standard deviation being the standard deviation of the differences.

The details of this approach have been described[7-12] and are included in the paper reprinted here in the pages following.[7]

Does it matter how device performance is expressed? Let us consider expressions in two papers recently published in this journal. In the first,[13] the authors report total error in two ways. One is bias ± precision, where precision is the 95% confidence interval for bias. This is 'fine' as far as it goes, but it tells us nothing about the error of individual measurements, which is important because we base clinical decisions on single values—not on averages of groups of readings. The authors also report the limits of agreement, which does say something about individual readings. However, their limits are calculated with sample sizes of as little as 15. To account for the errors in estimating bias and standard deviation for this sample size, the limits should be based on bias ± 3.529 standard deviations to be 99% confident (ie, not on bias ± 2 standard deviations). This means that their limits as reported are only about 60% of what they should be. This could make a real difference in deciding whether one measurement system can be substituted for another. In the other paper,[14] the authors report limits of agreement based on a sample size of 114. Their limits are underestimated by only 16%. When calculating with $k_1 = 2.327$ instead of 2, one of their intervals (for pH) falls outside the acceptable CLIA performance specifications on the low end.[15]

My point is, if you are going to report accuracy data, do it with as much accuracy as possible! Compared to the time it takes to conduct and publish a study, the time necessary to look up the appropriate value (rather than merely multiplying by 2) amounts to nothing!

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Evaluation of instrument error and method agreement

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"Measurement theory is the art of feeling confident about being in error."

Safely operating life support equipment and evaluating new technology both require some basic understanding of measurement theory. Measurement errors fall into two main categories: systematic errors (predictable problems usually due to calibration) and random errors (unpredictable). These two types of errors can be quantified by experiments involving repeated measurements of standards or "true" values. Systematic error (called bias) is usually expressed as the mean difference between measured and true values. Random error, called imprecision, can be expressed as the standard deviation of measured values. Total error can be expressed as an error interval, being the sum of bias and some multiple of imprecision.

An error interval is a prediction about the error of some proportion of future measurements (e.g., 95%) at some level of confidence (e.g., 99%) based on the variability of the sample data and the sample size. Specifically, a tolerance interval gives an estimate of the true value of some variable given repeated measurements with an assumed valid measurement system. An inaccuracy interval predicts the validity of a measurement system with an estimate of the difference between measured true values (given that a standard or true value is available for measurement). An agreement interval evaluates whether or not one measurement system (e.g., a known valid system) can be used in place of another (e.g., a new unknown system). Statistical analyses such as correlation and linear regression are commonly seen in the literature, but not usually appropriate for evaluation of new equipment.

Instrument performance evaluation studies should start out with a decision about the level of allowable error. Next, experiments are designed to obtain repeated measurements of known quantities (inaccuracy studies) or of unknown quantities by two different measurement systems (i.e., agreement studies). The first step in data analysis is to generate scatter plots of the raw data for review of validity (e.g., outliers). The next step is to make sure the data adhere to the assumption of normality. The third step is to calculate basic descriptive statistics, such as the mean and standard deviation.

Finally, the data should be presented in graphic form with the differences plotted against the reference values and including numerical values for the calculated error intervals. The key idea to remember is that device evaluation and method agreement studies are based on the desire to know how much trust we should place in single measurements that may be used to make life support decisions.

Key words: Degree of association, instrument evaluation, measurement error, method agreement.

Introduction

Clinicians must be familiar with the basic concepts of measurement theory in order to operate equipment effectively and to evaluate new technology. Concepts which should be understood are measurement error and agreement between measurement methods.

There are two fundamental methods of measurement: *direct comparison* with a standard and *indirect comparison* through the use of a calibrated system.[1] Measurements of length and weight are examples of the technique of directly comparing an object with an accepted standard (e.g., a ruler or standard mass). Ideally, the standard should be traceable (through three or four generations of copies) to the prototype kept by the National Institute of Standards and Technology (formerly the National Bureau of Standards).

Every measurement is assumed to have errors associated with it, if for no other reason than the true value of any quantity is unknowable. Even standards are simply the best estimate of a true value made from many carefully controlled measurements. In terms of measurement theory, errors fall into two categories: systematic errors and random errors.

Random errors occur in an unpredictable manner due to uncontrollable factors and cause measurements to both overestimate and underestimate the true value. The true value itself may vary slightly in a random fashion. As the number of repeated measurements of the same quantity increases, random errors tend to sum to zero. Hence the mean value of repeated measurements will converge on the true value. The Central Limit Theorem of statistics says that both the sum and the mean of a set of random values will have an approximately normal distribution if the sample size is sufficiently large.[2] This provides the basis for establishing the probability of a given measurement value and hence the confidence in the reliability of our observations.

Systematic errors occur in a predictable (although not always controllable) manner and cause measurements to consistently either underestimate or overestimate the true value. Systematic errors are not affected by the number of repeated measurements made but can be reduced by proper calibration. Calibration, however, does not improve random error.

The effects of measurement errors may be expressed as:

$$\text{measured value} = \text{true value} \pm (\text{systematic error} + \text{random error})$$

The observed measurement is seen as the sum of the true value and the errors.[3] The goal is to identify and minimize measurement errors.

Inaccuracy, bias, and imprecision

To avoid confusion regarding nomenclature, the term *inaccuracy* will be used hereafter to mean the total error of a measurement, *bias* to mean systematic error, and *imprecision* to mean random error. Therefore, a highly inaccurate measurement is one that is highly biased and/or highly imprecise (a scheme also used by Doebelin and by Bourke and associates.[4,5] Thus:

$$\begin{aligned}\text{measured value} &= \text{true value} \pm \text{bias} \pm \text{imprecision}\\ &= \text{true value} \pm \text{total error}\\ &= \text{true value} \pm \text{inaccuracy}\end{aligned}$$

It follows that:

$$\begin{aligned}\text{total error} &= \text{measured value} - \text{true value}\\ &= \text{bias} \pm \text{imprecision}\end{aligned}$$

If the inaccuracy for a given measurement is a positive number, we say that the measured value overestimates the true value and vice versa.

Error intervals

When evaluating new devices or methods, we are often interested in knowing how single measurements compare to either known values or other measured values from devices we accept as being accurate. This is because clinical decisions are often based on single measurements or at best a few consecutive measurements that show some consistency. Confidence intervals for population parameters such as the mean and standard deviation do not provide this information. We need analogous intervals, which we will call *error intervals*, that describe the combined effects of systematic and random errors on individual measurements and also say something about how much confidence we

should place in the estimate. Simply stated, we want some way to decide how much trust to place in an instrument reading.

Many studies involve the assessment of new devices or methods compared to existing standards, and there are many statistical concepts involved. We will simplify the subject and discuss only three cases. For example, when a new batch of blood gas analyzer control solutions is purchased, it is necessary to verify the manufacturer's specifications for the expected lower and upper limits of individual measured values for the analyte. If an individual measurement violates one of these limits, it may signal that the analyzer is malfunctioning.

The performance of a new blood gas analyzer might be evaluated by examining measurements of control solutions with known P_{O_2} values. If measurements produced the expected values, then the analyzer would be judged acceptable for use.

Another example might be comparison of P_{O_2} data from a new model of blood gas analyzer with measurements from a currently used blood gas analyzer. If measurements from the new analyzer agreed sufficiently with the same measurements from the old analyzer, we could confidently use the new analyzer in place of the old.

These are actually three different problems. In the first case, it is necessary to determine a range of values within which any given individual measurement should fall when measuring a known value, known as a *tolerance interval.* In the second case, we wish to determine the range of values for the *difference* between the known (assumed true) value and the actual measured value to assess the *inaccuracy* of the measurement system. In the third case, the true value is not known, so we can only assess the range of values for the difference between one measurement system and another to assess *agreement* (actually disagreement). However, in each case the error interval will have the form:

$$\text{error} = \text{bias} \pm \text{imprecision}$$

as described in the section on "Inaccuracy, bias, and imprecision."

Error intervals should not be confused with confidence intervals. Error intervals estimate the range of expected *individual measurement values,* whereas confidence intervals estimate the range of expected values of some statistical parameter such as the mean. Error intervals will be wider than confidence intervals because the imprecision of individual measurements is larger than that of population parameters (e.g., the standard deviation of individual measurements is larger than the standard error of the mean by a factor of $\sqrt{n}$.)

Tolerance interval

In assessing where *individual measurements* might fall, we are interested in determining the range of values which should include the true value with a specified degree of confidence. If the true mean and standard deviation of an infinite number of repeated measurements were known, then a two sigma (i.e., a two standard deviation) tolerance interval (TI) could be expressed as $TI = \mu \pm 1.96\sigma$. This interval includes exactly 95% of the observed measurements, and thus we can say with 95% confidence that the true value lies within this range of values. In this special case, the confidence level coincides with the proportion of measurements encompassed by the tolerance interval. However, μ and σ are unknowable. Therefore, we must substitute the appropriate point estimates $\overline{X}$ and S. Because of the random error involved with estimating the population mean and standard deviation, the proportion of the population of measured values covered by the tolerance interval is not exact. As a result, the confidence level must be calculated based on the uncertainty of the point estimates of the population parameters. The *tolerance interval* is thus expressed as:[6-8]

$$TI = \overline{X} \pm k_1 S$$

where $\overline{X}$ is the sample mean value and S is the sample standard deviation from repeated measurements of the known quantity. The factor k_1 is determined so that one can assert with the desired confidence that the true value lies within the specified tolerance limits.[7,8] The value of k_1 is selected from Table I by determining the confidence level and the sample size *n* (assuming that 95% of measured values will be included in interval; combined data from Walpole and Myers and Mason et al.[7,8]

Inaccuracy interval

A tolerance interval assesses the imprecision of measurements only. To assess the total error or inaccuracy of a measurement system, we need estimates of bias and imprecision from experiments in which known quantities are repeatedly measured. Bias is estimated as the mean difference between measured and known or assumed true values. Imprecision is estimated as the standard deviation of the differences between measured and true values. Inaccuracy is expressed as the sum of these bias and imprecision estimates. Thus we can construct an *inaccuracy interval* (II) in similar fashion to the tolerance interval:

$$II = \overline{\Delta} \pm k_1 S_\Delta$$

where $\overline{\Delta}$ is the mean difference between measured and true values and S_Δ is the standard deviation of

Table I

Factors for determining two sigma error intervals (i.e., intervals containing 95% of observed measurements); n = sample size

	Confidence level			Confidence level	
	95%	99%		95%	99%
n	k_1	k_1	n	k_1	k_1
2	37.10	185.61	45	2.41	2.63
3	9.85	22.27	50	2.38	2.58
4	6.36	11.13	60	2.34	2.51
5	5.08	7.86	70	2.30	2.46
6	4.44	6.35	80	2.27	2.42
7	4.01	5.49	90	2.25	2.38
8	3.73	4.94	100	2.23	2.36
9	3.53	4.55	150	2.18	2.27
10	3.39	4.28	200	2.14	2.22
11	3.26	4.05	Infinity	1.96	1.96
12	3.16	3.87			
13	3.08	3.73			
14	3.01	3.61			
15	2.96	3.52			
16	2.90	3.42			
17	2.86	3.35			
18	2.82	3.28			
19	2.78	3.22			
20	2.76	3.18			
25	2.64	2.98			
30	2.55	2.85			
35	2.49	2.75			
40	2.45	2.68			

the differences. The value k_1 is selected as described for tolerance intervals.

Agreement interval

We often need to know whether or not some new measurement system will give results comparable to one that is currently in use. We might like to know if the new system can serve as a substitute for the old while preserving the quality of medical decisions based on the system's measurements. Assessing agreement between two measurement systems is similar to assessing error, except that instead of repeatedly measuring one level of a known quantity, several levels of the known quantity are selected and split samples are measured by both systems. For example, in assessing the agreement between old and new models of blood gas analyzers, several samples of patient blood would be split in half and analyzed with each device. The mean difference between pairs of measured values is used along with the standard deviation of these differences to make a statement about agreement.

Bland and Altman have suggested a statistic called the "limits of agreement" which is the mean difference ± two standard deviations.[9] While this is easy to calculate, it is only a point estimate. That is, it does not take into account the uncertainty associated with the sample size, with smaller samples giving poorer estimates. Alternatively, an *agreement interval*, similar to the tolerance interval and the inaccuracy interval can be expressed as

$$AI = \bar{\Delta} \pm k_1 S_\Delta$$

where $\bar{\Delta}$ is the mean difference between measured and true values and S_Δ is the standard deviation of the differences. The value for k_1 is selected as described for tolerance intervals. Thus, the lower limit of agreement is $\bar{\Delta} - k_1 S_\Delta$ and the upper limit is $\bar{\Delta} + k_1 S_\Delta$.

Incorrect methods often used to evaluate agreement

The performance study techniques suggested by Bland and Altman[9] and Altman[10] are fortunately becoming popular among current researchers.[11-14] In the past, the most frequently used statistical analyses to assess the comparability of measurement devices were least squares linear regression, the *t* test, the F test, and Pearson's product moment correlation coefficient. However, there are several reasons why these techniques are inappropriate for agreement studies.[9, 10, 15, 16]

As mentioned above, least squares regression minimizes the sum of squares of the vertical distance between the observed data and the regression line. The underlying assumption is that only the data plotted on the Y-axis show variability. This assumption is appropriate for studies of inaccuracy where the reference values, plotted on the X-axis, are assumed to be known with negligible imprecision. However, it is not appropriate in the comparison of two methods that both exhibit variability. It can be argued that variability in the X-axis data can be accounted for by using the method suggested by Deming, which minimizes both the Y residual and the X residual by minimizing the sum of the squares of the perpendicular distances from the data points to the line.[16-18] However, regression still suffers from sensitivity to nonlinearity of the data and will give misleading results if the range of the data is too narrow (i.e., the best fit line is more strongly influenced by the scatter of the data for narrow versus wide ranges).[19] Also, it is considerably easier to calculate an agreement interval than to perform sophisticated regression analysis.

Both the *t* test (for differences between means) and the F test (for differences between standard deviations) are sometimes used as indicators of agreement, although they are only intended to tell whether the differences between two methods are significant. If the calculated value for the statistic

is larger than some critical value, the performance of the measurement system in question is judged not acceptable. If the statistic is smaller, it is usually concluded that the methods agree and the new system is accepted. Such judgments may be erroneous for several reasons.

The F test is simply the ratio of the variances of the data from two measurement systems. It is a comparison of error levels, indicating the significance of any difference, and not an indicator of the acceptability of errors nor of their magnitude.[15]

The *t* test is a ratio of systematic and random errors,[15]

$$t = \frac{\text{bias} \pm \sqrt{n}}{S_{\Delta}}$$

(where S_{Δ} is the standard deviation of the differences between paired measurements and n is the sample size) and therefore is not a measure of total error. This is analogous to the determination of blood pH by the ratio of bicarbonate to carbon dioxide tension.[15] A low pH does not tell whether the bicarbonate is low or the carbon dioxide is high. Treatment of acidosis requires assessment of both metabolic and respiratory factors. Similarly, interpretation of the *t* value requires assessment of both the systematic and random errors. There are at least four situations that that can cause erroneous judgments when using the *t* value:[15]

1. The *t* value may be small when systematic error is small and random error is large. Thus, the more imprecision there is in the measurement data, the more likely we are to conclude that the methods agree!

2. The *t* value may be small when both systematic and random errors are large.

3. The *t* value may be large when both errors are small, in which case the more accurate the measurements are, the less likely we are to conclude that the methods agree!

4. As shown in the equation above, *t* varies with the sample size (n). Thus, even if systematic and random errors are acceptable, we might conclude that the methods do not agree if the sample size is large and vice versa.

A further limitation of the *t* test is that it is an indicator of the significant difference between *mean* values. It provides no information about the confidence we can place in *individual measurements* taken with the new method.

Perhaps the most widely misused indicator of agreement is the product moment correlation coefficient, *r*. The fundamental problem with the statistic is that is is a measure of linear association which is not the same as agreement. For example, suppose we plotted the data from two methods that gave exactly the same results when measuring a range of unknown values. The data would all lie on the line of identity. The *r* value would be 1.0 (i.e., perfect correlation), and it would be clear that the methods had perfect agreement. However, if one method gave exactly twice the value of the other, or say, twice the value plus three units, the data would still lie on a straight line with $r = 1.0$. However, it would be quite obvious that the two methods do not agree as the regression line would be displaced from the line of identity and would have a different slope. The *r* value is an indicator of random error and is completely insensitive to systematic error.

There are other problems with the *r* statistic.[9] Correlation is sensitive to the range of the measurements and will be greater for wide ranges than for small ones. Because investigators usually compare methods over the whole range of values expected to be measured, a high correlation is almost guaranteed. Also, the test of a significance (i.e., that *r* is significantly different from zero) will undoubtedly show that the two methods are related as they are designed to measure the same quantity. The test of significance is therefore irrelevant to the question of agreement.

Instrument performance, evaluation studies

■ *Establishing standards.* Measurement system performance studies are intended to show how close a single measurement value will be to the true value and how much confidence can be placed in it. Before any judgment can be made, we must have decided beforehand what level of inaccuracy is acceptable. This decision can be both elusive and confusing. Standards for allowable error may be generated in several ways:

1. On the basis of the intended application—for example, a single oxygen analyzer used in an adult intensive care unit may have an allowable error ±2% of full scale because such a small discrepancy will have little clinical effect. However, measurement of oxygen concentration for the purpose of calculating gas exchange parameters requires much better accuracy. Norton has shown that an error of 1% in the measurement of oxygen concentration leads to an error of 24% in the calculation of oxygen consumption and 32% in the calculation of respiratory exchange quotient.[20] He therefore recommends an allowable error of 0.1% for oxygen analyzers used for these purposes. On the other hand, he demonstrates that an error of 5 torr (≈1%) in the measurement of barometric pressure leads to a negligible error (≈0.02%) in the conversion of volume from ambient temperature

and pressure, saturated, to body temperature, pressure, saturated.

2. On the basis of agreement with similar, commonly used measurement systems. (e.g., the acceptance of pulse oximetry on the basis of results comparable to in vitro oximeters).

3. By professional consensus (e.g., standards set by the American Thoracic Society and the International Standard Organization).

4. By arbitrary statistical methods (e.g., if the standard deviation of the measurement method is one fourth or less of the normal population standard deviation, then analytic imprecision may be judged to be negligible[17]).

Note that even if the allowable error can be agreed upon, it is important to know the value or range of values of measured quantities that represent cut-off points for medical decisions. For example, an imprecision in transcutaneous PO_2 readings of ±15 torr might be reasonable for PO_2s above 100 torr but would not be adequate for lower values in the range that might indicate hypoxemia.

■ ***General experimental approach.*** A complete examination of experimental design is beyond the scope of this discussion. In general, however, pairs of data (i.e., measured versus known values or values from two methods for a given level of input) should be gathered over a wide range of input levels (one data pair per input level). These data will provide information about bias and some information about imprecision. Additional data pairs may be gathered from repeated measurements at selected input levels (i.e., critical levels corresponding to cut-off points for making decisions) to provide better estimates of imprecision. The sample size for a given experiment will be limited by many practical factors but should be no less than 20, with larger samples being preferable.[19]

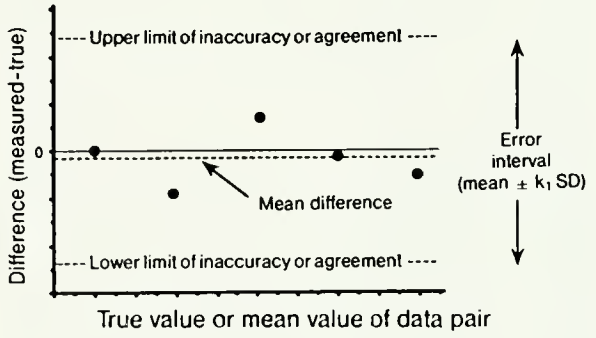
Experiments should be planned with a consideration of the possible sources of bias and imprecision (discussed above). For example, to estimate the inaccuracy expected in the normal daily operation of a measurement system, data should be collected over the entire range of measurements that will be used clinically and over a period of days to account for errors due to the magnitude of measurements and to variations in environmental and operator factors and even calibration errors. On the other hand, if the inaccuracy of the system alone is desired, repeated measurements of the same quantity should be made within a short time frame with all other confounding factors held as constant as possible.

■ ***Data analysis procedure.***

Step 1: The first step in any data analysis should be to create a scatter plot of the raw data to get a subjective impression of their validity. The mean and standard deviation of the data should be calculated and used to identify outliers (see below). When determining tolerance intervals, the data should be plotted along with the data mean and standard deviation. For inaccuracy analysis, the difference between the true (i.e., known or standard) values and the measured values should be plotted on the vertical axis against the true values on the horizontal axis. For agreement analysis, the differences between measurement pairs using two measurement systems are plotted against the mean values of each pair (Figure 1). The mean values are used as the best estimates of the true values which are not known.

Figure 1

Suggested format for plotting data values and error intervals for inaccuracy and agreement studies


Upper limit of inaccuracy or agreement
0
Mean difference
Lower limit of inaccuracy or agreement
Difference (measured-true)
Error interval (mean ± k1 SD)
True value or mean value of data pair

The purpose of these plots is not only to identify any outliers but to make sure that, for inaccuracy and agreement studies, the differences are not related to the true (or mean) values (i.e., to the measurement level). If they are, the standard deviation of the differences may be overstated at one point of the range and understated at another. In other words, calculation of one value for standard deviation should adequately describe the variability of the data over the whole range of measurements. It might be possible to circumvent this problem by using a logarithmic transformation of the data.[9]

Alternatively, one could derive worse-case error specifications as a percentage of full scale reading like some manufacturers do. The hypothesis that the differences are not correlated to the measurement level can be tested formally with the Pearson product moment correlation coefficient, a standard procedure described in any introductory statistics textbook.

Step 2: The next step is to make sure the data

comply with the assumption of normality (i.e., they are adequately described by the normal or Gaussian distribution). All of the statistical procedures described hereafter are based on this assumption. The data can be assessed for normality using either graphical (i.e., plotting the data on normal probability graph paper) or statistical (chi square or Kolmogorov-Smirnov) tests,[1, 17] It may be sufficient to simply graph the frequency distribution and make a subjective judgment as to whether or not it is "bell shaped."

Step 3: Once the data are judged to conform to the underlying assumptions, the mean and standard deviation are used to calculate error intervals as described above.

Step 4: Finally, the data should be presented in graphic form and labeled with the numerical values for the error interval limits.

■ ***Treatment of outliers.*** Spurious data may be caused by temporary or intermittent malfunctions of the measurement system or operator errors. Such errors should not be included in the error analysis. The plot of the data should be inspected for outliers or values that depart from the expected distribution. Outliers at the upper and lower limit of the range will have a strong effect on the estimates of systematic error. Outliers near the center of the range will have a strong effect on the estimate of random error. Any of the sources of error mentioned previously can cause unusually large deviations from the desired linear relation. Outliers are identified as any measurement that is more than k_2 standard deviations from the mean, where k_2 is based on the sample size (Table II).[21]

Table II

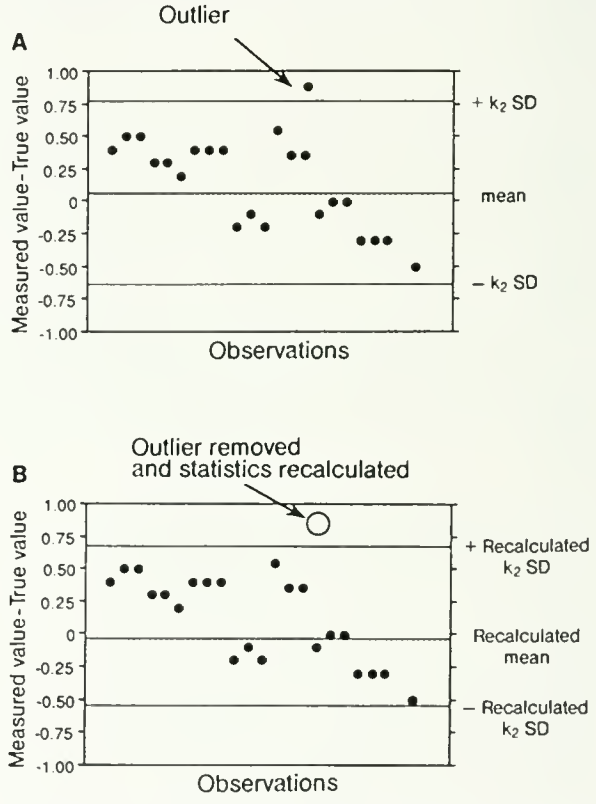
Factors for determining outliers in raw data at the 95% confidence level

n	k_2
5	1.57
10	1.80
12	1.83
14	1.85
16	1.87
18	1.88
20	1.89
25	1.90
30	1.91
40	1.92

Any occurrence of an outlier should be examined for evidence of a real source of nonlinearity rather than a spurious error. The occurrence of more than three unexplained outliers per 100 observations suggests that there may be a serious problem with the measurement system.[17] Outliers are eliminated from the data set one at a time until no more are identified. Each time an outlier is rejected, a new mean and standard deviation are calculated for the reduced sample (Figure 2).

Figure 2

Treatment of outliers using example data



(A) The mean and standard deviation (SD) are calculated from the original data set. The data are plotted along with limits calculated based on the sample standard deviation and the factor k_2 (see Table II). An outlier is identified as any data point(s) lying farther than k_2 standard deviations from the mean.

(B) The outlier is removed from the data set, and a new sample mean and standard deviation are calculated along with new outlier limits. The new data set is inspected, and no new outliers are identified. If outliers existed, they would be removed and the process repeated until no outliers remained.

Summary

The key idea to remember is that device evaluation and method agreement studies are often based on the desire to know how much trust we should place in single measurements. Common statistical procedures such as the creation of confidence intervals, correlation coefficients, or linear

regressions are not appropriate because they describe group characteristics (e.g., mean values) rather than express the validity of individual measurements. More useful are error intervals, which describe the expected error of a given measurement along with a probability statement regarding the confidence we can place in the error estimate. The three basic types of error intervals are:

1. Tolerance interval—a range of values that measurement of a known quantity might yield.

2. Inaccuracy interval—a range of values for the difference between a measured value and the true value.

3. Agreement interval—a range of values for the difference between readings of two measurement systems.

Error intervals help us to judge the wisdom of using single measurements for important clinical decisions.

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'Breathing Room': Why Critical Care Ventilator Manufacturers Should Be Exempt from Design-Defect Strict Liability in California

Introduction

Positive pressure ventilation is central to the practice of modern critical care medicine. Design of the machines providing this type of ventilation has steadily improved since they were first conceived 40 years ago. These devices artificially provide ventilation and oxygenation to patients who can no longer naturally support their respiratory needs. Needs change dramatically as a result of lung injury from causes spanning the entire spectrum of human existence—from prematurity in infants to the elderly with pneumonia. The need to care for trauma victims, organ transplant recipients, and those suffering from burns speaks to the complexity of modern life and thus to the complexity of modern medicine. Medical problems arising from these and other issues hint of the complexity of the devices needed to support ventilation and oxygenation safely. Positive pressure ventilators have steadily improved through four recognizable generations of design.

This growth and development of mechanical ventilators occurred during a period of time when financial support, medical research support, and legal support were in place and reasonably dependable. Today (1996), manufacturers of positive pressure ventilators contemplate organizational 'downsizing' and a cutting back on production. It is no longer economical to continue to improve and produce these ventilators in the United States. Some larger ventilator companies are moving their operations outside the U.S. The difficulties these companies encounter include the financial drain caused by having to pay high insurance premiums and the costs to test and market their medical devices. For example, the Food & Drug Administration (FDA) imposes "good manufacturing practices" (GMPs) and other regulations to protect the consumer—regulations that increase the cost of each ventilator unit produced.

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Manufacturers also experience 'legal' pressures due to strict products liability laws. In California, for example, a ventilator manufacturer can be held liable for damage awards even if the ventilator is not defective in the conventional sense. An injured plaintiff need only prove that a product has a defective design and that his or her injuries were caused by the alleged defect. All of the manufacturer's prior efforts, including design, testing, and clinical trials become irrelevant in a design-defect action. Lawsuit restraints (ie, statute of limitations) are calculated from the date of a patient's injury and not from the date of the device's manufacture. Hence, a manufacturer is not protected by a statute of limitations if its product does not injure within a certain time period. Liability attaches if the device does not meet the "consumer's expectations" (ie, the patient's expectations) or if the "risk of the particular design outweigh the benefits of the design."

Critical care device manufacturers desire nothing more than a 'level-playing field' on which to produce their life-saving devices. In this paper we explore two issues:

- Does it make sense to apply design-defect strict liability to positive pressure ventilator manufacturers?
- If it makes no sense, does California law support an exemption for manufacturers of positive pressure ventilators?

Design-Defect Strict Liability & the *Brown* Exception

Public Policy behind Design-Defect Strict Products Liability

Public policy considerations underlie strict products liability in California. As first espoused by Justice Robert Trainer in *Escola v. Coca Cola Bottling Company*, (1944) 24 Cal.2d 453, consumers generally cannot anticipate or guard against injuries caused by defective products. (*Escola* involved an exploding soft drink bottle.) Manufacturers are better equipped to anticipate such hazards and can insure against the risk and also distribute the cost among members of the consuming public. Strict liability furthers the public interest by discouraging the marketing of defective products. Strict liability, therefore, focuses not on the conduct of the manufacturer but on the product itself. In *Barker v. Lull Engineering Company* (1978) 20 Cal.3d 413, 143 Cal. Rptr. 225, 573 P.2d 443, the California Supreme Court for the first time described the con-

cept of design defect. (The issue in *Baker* was whether a high lift loader was unsafe because it toppled during a lift on sloping ground.) According to the court, certain products are "perfectly" manufactured but are still unsafe because of their design. The Court found that a product is "defectively designed" if it fails to perform as safely as an ordinary consumer would expect when the product is used as intended or if the risk of danger inherent in the design outweighs the benefits of the design.

Design-defect strict liability, by its very nature, involves a struggle between *accountability* and *availability* of the particular product. The specter of design-defect liability necessarily causes delay in the marketing of products while manufacturers conduct additional safety tests. Strict liability can deter research, manufacturing, and marketing altogether. However, in many cases, strict liability can be *socially beneficial* to the public. As stated by one appellate court "We are often willing to sacrifice speedier marketing of products, or we may be willing to sacrifice availability altogether, in return for greater *accountability* of manufacturers through imposition of strict liability." (*Kearl v. Lederle Laboratories* (1985) 172 Cal. App.3d 812, 823, 218 Cal. Rptr 453.)

The *Brown* Exception—Public Policy Not Furthered by Strict Products Liability

The California Supreme Court has carved out an exception to this rule. In *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 245 Cal. Rptr. 412, 751 P.2d 470, the court held that prescription drug manufacturers are not strictly liable for injuries caused by prescription drugs provided the product is properly prepared and accompanied by warnings of its dangerous propensities that are either known or reasonably knowable at the time of distribution. The Court refused to apply design-defect liability for one overriding reason—it was not in the public interest to do so. The public interest in the availability and affordability of prescription drugs outweighed the public interest in manufacturer accountability.

Citing Comment k of Section 402A of the Restatement Second of Torts, the Supreme Court noted certain products, such as drugs, are incapable of being made safe for their intended use, yet are not unreasonably dangerous. Such products cannot generally be sold except to physicians or under prescription of a physician. Strict liability, therefore, should not apply to such products (*Brown, supra,* 44 Cal.3d, pages 1058-1059).

The *Brown* decision also rejected the "consumer expectation" and the "risk benefit" tests as applied to the manufacturers of prescription drugs. The consumer expectation standard is inappropriate because the 'consumer' is not the plaintiff, but rather the prescribing physician is the plaintiff. It seems clear in the prescription drug context that the injured plaintiff is not in the same position as the physician to whom all of the drug manufacturer's warnings and the product information are directed. The Court likewise rejected the risk benefit test because of competing policy goals. Unlike typical products that are used to make work easier or to provide pleasure, drugs and other medical products may be necessary to alleviate pain and suffering or to sustain life (*Ibid,* page 1063).

Further, unlike other important medical products, such as wheelchairs, harm to some users from prescription drugs is unavoidable. Strict products liability could delay the marketing of new drugs even though public policy favors swift development and marketing of new drugs to save lives and reduce pain and suffering. Drug manufacturers might be reluctant to undertake new research programs and develop new products because of the fear of large adverse monetary judgments based upon strict liability. The expense of insuring against such liability could place the cost of medication beyond the reach of those who need it most and deter other manufacturers from even entering the market (*Brown,* supra, 44 Cal.3d, pages 1063,1064). In short, the Supreme Court of California found a "broader public interest" in the *availability* of drugs at affordable prices.

The *Brown* Exception Extended to Implanted Medical Devices

Recent California appellate decisions have extended the *Brown* rationale to manufacturers of implanted medical devices. In *Hufft v. Horowitz* (1992) 4 Cal.App.4th 8,5, Cal.Rptr.2d 377, Division Three of the Fourth Appellate District Court of Appeal found that strict products liability does not apply to a manufacturer of inflatable penile prostheses. Citing *Brown,* the *Hufft* court found that risks attendant to implanted medical devices are akin to those of prescription drugs. Like drugs, such devices must be "plugged-in" to the individual to "work their effect upon or respond to complex systems imperfectly understood by medical science." Implanted medical devices, such as the penile prosthesis, do more than provide mere comfort or assistance to a patient; they become "an integrated part of the person." Like drugs, the public interest in development, availability, and affordability of such devices demands rejection of strict liability (*Ibid,* pages 18-19).

That same year, Division Two of the Fourth Appellate District rejected the application of strict liability against the manufacturer of an intrauterine device (IUD) in *Plenger v Alza Corporation* (1992) 11 Cal.App.4th 349, 13 Cal.Rptr2d 811. Again citing *Brown,* the Court noted that strict liability for design defect is based primarily, if not exclusively, on public policy considerations. The Court reasoned that the same public policy concerns described in *Brown* apply to devices such as an IUD (*Ibid,* pages 359-360).

More recently, in *Artiglio v. Superior Court* (1994) 22 Cal.App.4th 1388, 27 Cal.Rptr.2d, Division One of the Fourth Appellate District again applied the *Brown* rationale to manufacturers of breast implants. As in the previous cases, the court noted that a breast implant is "plugged-in" to the indi-

vidual and poses the potential for harm both in its interaction with bodily systems and its implantation and possibility of removal. As in the previous cases, the Court found the public interest better served by providing effective and affordable medical implants than by imposing strict liability (*Ibid*, page 1395).

The *Artiglio* court also stressed that such implants carry the further protection of "prescription," which provides "insulation between the manufacturer and the user so as to warrant elimination of consumer protections under strict products liability" (*Ibid*, page 1397). In making this comment, the *Artiglio* court seemed to follow the "Learned Intermediary Doctrine," embraced by other jurisdictions, that exempts the application of strict liability to medical devices available only through the order of a physician.

These rulings demonstrate how the appellate courts, particularly the Fourth Appellate District, have already begun to expand the application of *Brown* from prescription drugs to prescribed medical products that have nothing to do with drugs.

We believe that positive pressure ventilators possess the same characteristics as drugs and "implanted medical devices." Like a drug or implanted device that is placed in the body and "reacts" with complex body systems, a positive pressure ventilator must be "plugged-in" to the individual through the use of tubing that is placed into the patient's trachea to begin the ventilation process. The ventilator then assumes the patient's breathing functions to achieve life-sustaining respiration. Positive pressure ventilators, therefore, automatically affect "complex bodily systems" and become "an integrated" part of the respiratory and cardiopulmonary systems of the person on the ventilator.

Further, as with drugs and implanted devices, risk is always present with positive pressure ventilation. Because the body naturally breathes by utilizing negative (ie, subatmospheric) pressure, positive pressure ventilation unnaturally forces air into the lungs potentially causing at least some barotrauma (injury due to the effects of pressure) to the patient. Other risks to the patient include the possibility of improper settings related to flow, pressure, and oxygen concentration. Other complications can occur during intubation and extubation. Any of these settings alone or in combination can cause permanent damage or even death.

Similar to drugs and implanted medical devices, positive pressure ventilators carry inherent risk because they are attached to the body at a time when the physiology of the critically ill person is unknown or, at best, uncertain. This integration into the respiratory system is done only when ordered by a physician who, we believe, then becomes the legal consumer of the product.

Public Policy & Positive Pressure Ventilators

As already shown, strict liability is based on public policy and can be extended to an even wider issue of public policy. The Supreme Court in *Brown* merely found that public policy interests would not be served by applying design-defect strict liability to the manufacture of drugs.

We believe that the same reasoning logically applies to the manufacturers of positive pressure ventilators. Like drugs described in *Brown*, positive pressure ventilators are medical devices defined under the Federal, Food, Drug, & Cosmetic Act and are regulated by the FDA. They can be used only under the authority and supervision of medical professionals. Like drugs, positive pressure ventilators are used to alleviate pain and suffering and are used in life-sustaining situations for critically ill patients. It can be argued that such ventilators are closer to the reasoning in *Brown* than are the medical devices described in *Hufft*, *Plenger*, and *Artiglio*. Neither a penile prosthesis, an IUD, nor a breast implant appears to be directly related to "alleviating pain and suffering" or to be a "life-sustaining" product as is a positive pressure ventilator.

The key public policy concerns described in *Brown* apply with equal force to the manufacturers of positive pressure ventilators. We believe that the public's interest is best served by having ventilators *available*, and this availability issue outweighs the strict *accountability* of the manufacturer.

Similar to the manufacturing of drugs, the FDA, through promulgated regulations (21 CFR 800 et seq) permeates every aspect of the production of positive pressure ventilators. The FDA can order a manufacturer to provide notice of a danger or to recall its medical device if the device presents a risk of illness or gross consumer deception (21 USC 360h). Given the broad controls that the FDA can exercise over the manufacturing of medical devices, such as positive pressure ventilators, accountability is not lost by the creation of a design defect exemption for life-sustaining devices.

Twenty years ago, many more U.S. companies manufactured ventilators than do so today. The five leading manufacturers of positive pressure, critical care ventilators are located in California. We believe that the application of strict products liability has already discouraged these manufacturers from aggressive research and the development of new ventilators. Anesthesia machines, first cousins of critical care ventilators, are now manufactured almost exclusively outside the U.S. One ventilator manufacturer is beginning the process of moving some of his operation to Europe because of the harsh regulatory and legal atmosphere encountered in the U.S. Strict liability litigation has had such a chilling effect on another manufacturer that his company has ceased making ventilators at all.

Manufacturing and insurance premium costs have skyrocketed. Strict liability has results in the manufacturing of fewer ventilators, which has increased their cost and lessened their availability. It is the public that ultimately suffers from the application of strict products liability to manufacturers of critical care ventilators. As in *Brown*, the need for availability of these important life-sustaining products should outweigh the need for accountability, particularly in view of the

broad FDA protections associated with the production of medical devices.

Conclusion

Under current California law, the manufacturers of prescription drugs and "implanted medical devices" are exempt from strict liability for design defect. Positive pressure ventilators share the same characteristics as the drugs and implanted medical devices now afforded protection. Positive pressure ventilators:

- are prescribed products that can be used only upon the order of a physician/clinician;
- are life-sustaining products as opposed to medical devices that make work easier or provide pleasure;
- are plugged into the individual and, thus, affect the "complex respiratory system" and become an "integrated part of the person;"
- involve inherent risks because of the very nature of the product;
- are regulated by the FDA and are subject to recall orders.

Most importantly, as described in *Brown*, public policy seek to encourage the research and development of effective and affordable prescription medical devices, such as positive pressure ventilators. Strict liability discourages research and marketing of newer devices, raises insurance rates for manufacturers, and often forces such manufacturers out of business. Because such ventilators are life-sustaining and vital to the well being of critically ill patients, the law should be applied in a way that encourages *availability* and the technologic *evolution* of these products. The law should not discourage necessary research, development, and marketing of these life-saving devices. A California maxim says it best: "When the reason for a rule ceases, so should the rule itself." (Cal. Civ. Code-3510.)

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Editor's Note: The authors and the editor invite the expression of opposing positions (or the support of their position) as a formal Point of View or in Letters to the Editor.

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A Question about Reporting Oxygen Concentrations

I read with great interest the report of Dennison et al of their evaluation of the $ServO_2$ Oxygen-Control system.[1] However, I had one concern in their reporting of the values obtained with their mass spectrometry system. They state in the text that the instrument has an accuracy of ± 1%. They then report all their oxygen percentage values to tenths (ie, one decimal place). They also say, for instance, that an oxygen concentration started at 23.2% and then dropped to 22.5%. As I understand it, one should not report values with greater accuracy than that of which the instrument is capable. Therefore, values should have been reported to the nearest whole number and there is *no* difference between values of 23.2% and 22.5%.

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REFERENCES

1. Dennison F, Brudno DS, Lain D, Kremenchugsky V. Bench evaluation of the $ServO_2$ oxygen control system. Respir Care 1996;41(8):724-727.

The author replies:

In reply to the query by Robert R Fluck Jr, I believe technically that he is correct. However, I have always had a problem with this textbook answer for the following reasons. When instruments report an accuracy of ±1%, they often give a digitized readout of analog data, as in our study, in tenths of a percent. How then does one accurately report data such as 22.5%? Do we arbitrarily round 'up' or do we round 'down'? To me, one method is as erroneous as the other, and textbooks seem to ignore the problem. So my answer is to ignore the textbooks! Furthermore, I always assume that if a researcher reports his instrument's measurements in tenths, such as 22.5%, with a reported instrument accuracy of ±1%, then the reader can assume any value from 21.5% to 23.5% with a high probability.

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A Question about Gas Consumption Calculations

I read with interest Op't Holt's report of his evaluation of the Bird Avian transport ventilator in the August issue.[1] I do, however, have a concern regarding his determination of ventilator gas consumption. As he does not specify the settings, I must assume he used the ones specified in the test for battery life and alarm function (f = 12, V_T = 600 mL). Assuming 185 minutes of operation ("just over three hours" as mentioned in the text), this would mean that delivered minute volume consumed 1,332 liters of gas for each ventilator. Ventilator gas consumption for the one ventilator would be 703 L during the test period. If we added this to the gas used for the minute volume, this is less than one third of a K cylinder. He does not specify how the pressure drop was measured in the cylinder. If he used the standard gauges for his K cylinder, an error of 100 psi would be possible. This would result in overreporting gas consumption by 314 L, or about 1.7 L/min over the measuring period. This would drop the one ventilator's consumption to 2.1 L/min (within the manufacturer's specifications) and the other's to 4.9 L/min, still clearly over specs.

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REFERENCES

1. Op't Holt TB. An operational evaluation of the Bird Avian transport ventilator. Respir Care 1996;41(8):714-723.

The author responds:

I agree with Mr Fluck's observation that measurement of gas pressures in the K cylinder using a standard pressure reducing valve could result in an error when calculating gas consumption. During this particular test, I allowed the ventilator to run such that the pressure gauge needle moved from the center of one pressure gauge marking until it was clearly in the center of a lower pressure gauge marking. If our pressure gauge is inaccurate or nonlinear, an error could occur. This would result in under- or overreporting of gas consumption. However, I had no way of verifying the pressures measured by our pressure gauge. It is clear to me that there was a difference in gas consumption between the two ventilators. This potential problem could be reviewed in a future study on clinical application.

Therefore, I maintain that ventilator users should periodically determine ventilator gas consumption in order to predict duration of gas supply, as a quality control measure.

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Managing the Patient-Ventilator System Using Graphic Analysis: An Overview and Introduction to *Graphics Corner*

Jon O Nilsestuen PhD RRT and Ken Hargett BS RRT

INTRODUCTION
- Background
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  - Synchrony
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- Graphic Displays

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USING RESPIRATORY MECHANICS IN WEANING
- General Considerations
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  - Measures of Strength
  - Measures of Endurance

IN CONCLUSION

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INTRODUCTION

Background

Since the introduction of mechanical ventilators, the interactions between patient and mechanical ventilator have been poorly understood and frequently mismanaged. The ventilator coupled with patient pathology has sometimes been the source of additional patient trauma. Engineers have

sought to design machines that are more patient friendly while clinicians have struggled to utilize all of the ventilator's capabilities. The advent of ventilator-generated graphics has added a new dimension to ventilator management. As clinicians become better versed in graphic analysis and clinical researchers define more advanced applications for using the available information, ventilator management should become more refined.

Technology has changed both the functional characteristics of mechanical ventilators and the monitoring and evaluation instruments that are available to assist clinicians in making decisions at the bedside. Although these newer attributes, such as flow sensitivity and pressure and flow monitoring, add a degree of complexity to the care of patients receiving mechanical ventilation, they can take away much of the guess work involved in adjusting the ventilator. We believe that waveform analysis allows the clinician to make objective observations and to fine tune ventilator variables that increase patient comfort and reduce the work of breathing. In this paper, we review the technical changes that have been made to ventilators and illustrate how graphic analysis can be used to evaluate the patient's response to the ventilator and to assist the clinician in making ventilator adjustments. In addition, we describe the range of variables that are included in ventilator monitoring packages, including aspects of pulmonary mechanics, such as compliance, resistance, work of breathing, maximum inspiratory pressure, and the rapid shallow breathing index.

Two freestanding devices (Ventrak—Novametrix, Wallingford CT, and BiCore—Allied Healthcare Products, St Louis MO) also offer graphic displays—scalars and loops—and measures of mechanics. These devices are also microprocessor driven and incorporate menus to assist the clinician in accessing the different attributes of the device. They also include alarm functions, trend analysis, and reporting capabilities.

Clinicians using the early mechanical ventilators relied heavily on manometers with rotating-needle dial and circular pressure scale and extrinsic flow- and volume-measuring devices (such as the Wright respirometer) to measure tidal volume and minute ventilation. These tools provided 'snapshots' or 'spot checks' that helped to characterize ventilation overall but were unable to provide continuous measurement or waveforms. Current-generation ventilators provide graphic depictions (ie, waveforms) that are continuously displayed on the monitoring screen; these depictions can be useful for fine tuning or customizing the ventilator breath to more adequately meet the needs of the patient.

Customizing the Mechanical Breath

Customizing the mechanical breath involves adjustment of three primary patient-related components: (1) triggering, (2) synchrony, and (3) patient-simulated flow.[1]

Triggering

Triggering refers to the manner of initiating the mechanical breath. In order to deliver breaths in response to patient need, the ventilator must sense patient effort. Whether triggering occurs appropriately depends on how well the ventilator 'senses' that effort and how rapidly it responds. Triggering is coupled to gas delivery through two primary mechanisms—pressure-sensing and flow-sensing.[2,3] With pressure-sensing, the ventilator senses the drop in airway pressure created by the patient's attempt to draw gas through the airway; whereas with flow-sensing, the ventilator senses the movement of gas in the circuit that accompanies that attempt. Sensitivity refers to the relative ease with which the patient causes the ventilator to cycle. (Figs. 1,2).

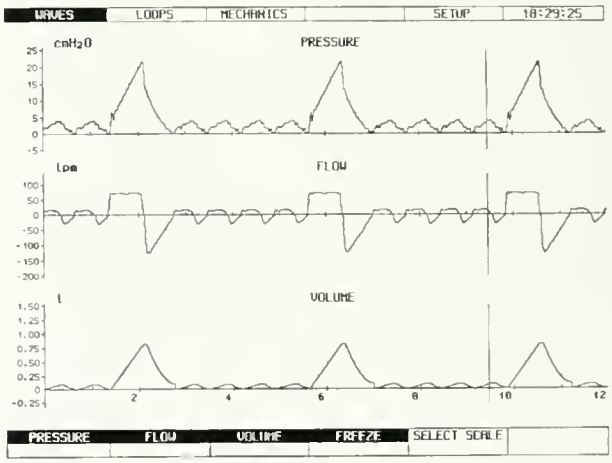

Fig. 1. The standard three-scalar display with pressure, flow, and volume graphed with respect to time. The trace also illustrates the results of adjusting machine sensitivity until the machine autocycles. Three machine breaths are shown with smaller pressure-supported breaths in between. Pressure support = 5 cm H_2O; sensitivity = 0.5 cm H_2O.

Synchrony

Synchrony refers to the timing of the machine breath with patient effort. Although timing of the machine breath to coincide with patient effort may seem simple at first glance, timing the ventilator breath becomes more complicated when the ventilator must distinguish between machine-initiated breaths and patient-initiated breaths. Mandatory breaths guarantee delivery of a preset volume or pressure and are controlled by the ventilator; spontaneous breaths[2] are breaths in which the patient initiates the breath and controls the size of the breath and the rate at which gas is delivered (Figs. 3,4). Accommodation of the spontaneous breaths of mechanically ventilated patients originally involved an external T-piece with 1-way valves that allowed the patient to draw air from the

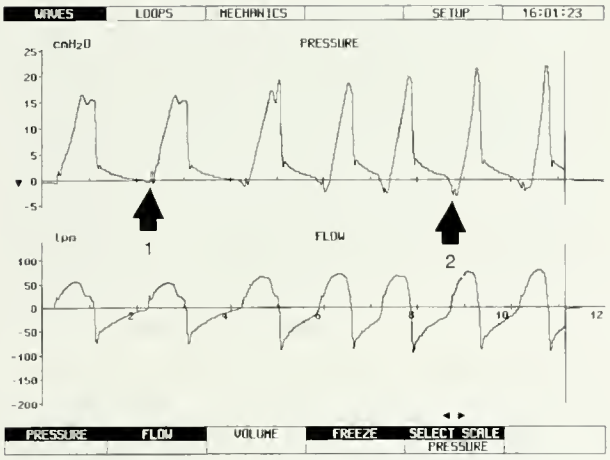

Fig. 2. Changes in patient effort during pressure-cycled breaths (effort increasing to the right). The sensitivity is set at 1 cm H_2O, pressure slope –5; pressure support 15 cm H_2O. Optimal cycling is illustrated during the first breath (Arrow 1); however, as patient demand increases, gas flow at the flow-valve setting (pressure slope) is unable to meet patient demand. The patient is pulling gas from the circuit faster than the valve can supply gas resulting in a greater pressure drop during the first portion of the breath until the valve can be more fully open (Arrow 2). Similar negative pressure swings can also be observed early in a pressure trace when the sensitivity is set incorrectly (ie, not sensitive enough). The pressure below baseline required to cycle the ventilator can be adjusted.

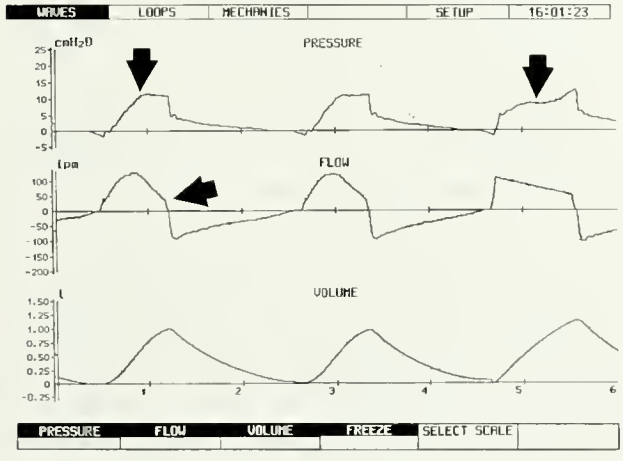

Fig. 3. The flow pattern during synchronized intermittent mandatory ventilation (SIMV) with pressure support. The first two breaths in the sequence are pressure-supported breaths; the last breath is a mandatory breath illustrating the decelerating flow pattern. During the pressure-supported breaths, the flow is largely determined by patient effort; however, the volume is not guaranteed. Note the pressure plateau (top arrow) characteristic of a pressure-supported breath and the termination of the pressure-supported breath at 25% of peak flow (arrow on the middle flow trace). The slightly concave appearance of the pressure trace on the third breath (Rightmost Arrow) indicates that flow toward the end of the breath does not meet patient demand.

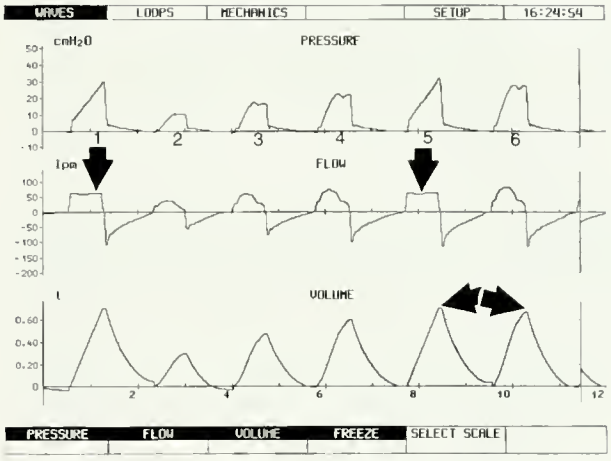

Fig. 4. Adjusting Pressure Support: In this case, a larger tidal volume was desired during pressure-supported breaths. The pressure was increased incrementally until the volume achieved during the patient-initiated breath (6) matched the volume delivered during the machine square-flow breath (1 & 5), a condition referred to as maximum pressure-support (PSV_{max}).

room air or a mixture of air and oxygen from a reservoir bag at any time.[4] With the addition of positive-end expiratory pressure (PEEP) and other modes of ventilation, the external tubing and circuitry became increasingly complex and manufacturers sought other means of delivering patient breaths, leading to the development of internal flow valves responsive to patient effort.

Timing the delivery of the mandatory breath was originally achieved by cycling the ventilator after a fixed period of time had elapsed, as determined by the rate setting. With a fixed time period, however, the ventilator frequently cycled into inspiration 'on top of' the patient's already initiated breath (commonly referred to as stacking breaths) or too early into the patient's exhalation. This lack of synchrony was associated with clinical complications including lung overdistention and patient discomfort. These problems have subsequently been resolved, at least partially, by the development of synchronized intermittent mandatory ventilation (SIMV, Fig. 5).[5] SIMV allows the ventilator to cycle in synchrony with known patient effort or during those periods when the patient is not attempting to initiate a breath. This helps to avoid stacked breaths.

Patient work of breathing (WOB) is affected both by triggering and by synchrony characteristics.[6] Figure 6 illustrates the relationship between patient effort as illustrated by the esophageal pressure trace and the volume delivered by the ventilator. During conditions in which the ventilator fails to trigger or the ventilator cycles out of synchrony with the patient, the patient performs unrewarded pressure work.[7] This additional work may prevent the patient from weaning or cause unnecessary discomfort or secondary hemodynamic changes.

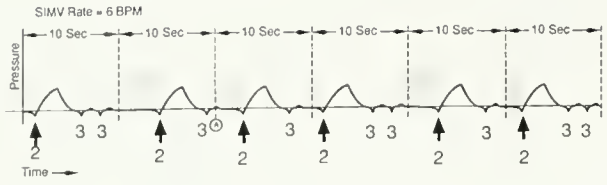

Fig. 5. The pressure trace graphed with respect to time illustrates the time period or 'window' during which the ventilator is sensitive to patient effort during synchronized intermittent mandatory ventilation, or SIMV. If patient effort is exerted at any time during the window, a machine breath (2) is delivered in synchrony with patient effort. If no patient effort is exerted a machine breath is delivered at the end of the time window. Notice the variance in the time window (shaded area) as the ventilator waits for the patient to initiate the breath. Spontaneous breaths to which the machine does not respond are indicated by (3).

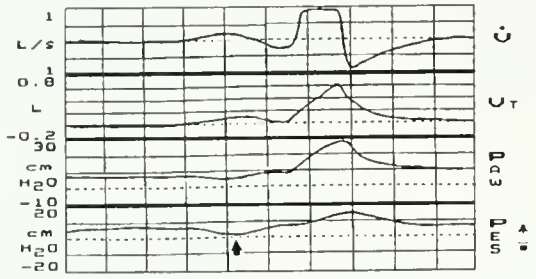

Fig. 6. Trace from the BiCore monitoring device. The pressure generated by the patient is identified on the esophageal pressure trace. This patient was placed on assist-control with positive end-expiratory pressure (PEEP) of 8 cm H_2O and sensitivity –5 cm H_2O. During the initial patient effort (arrow), the pressure is insufficient to trigger the machine. Only small amounts of gas are removed from the ventilator circuit, followed by the machine's mandatory breath.

Patient-Simulated Flow

Patient-simulated flow refers to delivery of gas from the ventilator in a flow pattern that mimics or reflects the flow pattern generated by the patient. The optimal flow pattern for delivery of gas to the patient has been a subject both of debate and of scientific inquiry for as long as mechanical ventilators have been around. Over the years, three primary flow patterns have been developed, tested and incorporated into ventilators: square, decelerating, and sinusoidal. However, with the advent of microprocessors it became possible to tailor ventilator flow delivery to more nearly match the flow demand of the patient.[8] This flexibility finally allowed inclusion of patient-related characteristics in the determination of the flow pattern and has led to a new generation of ventilator modes that offer patient-simulated flow.[9]

Figure 3 illustrates the flow pattern generated by a patient in the process of being weaned who has been placed on SIMV with pressure support. During the pressure-supported breaths, gas is provided by a demand valve within the ventilator—a valve that senses pressure or flow changes in the circuit created by the patient and supplies gas to the patient in proportion to these changes. If the patient requires additional ventilatory assistance, more pressure support can be selected on the ventilator. In this mode, the size of the patient breath (volume) and the flow pattern are largely determined by the patient's characteristics.[10] The waveform assumed by the gas is determined by: (1) the amount of patient effort—more effort results in higher peak flow; (2) the pressure selected on the ventilator, which also affects the total volume delivered—higher pressure results in greater volume; and (3) the mechanical characteristics of the patient's lung—the compliance and resistance that affect how easily and rapidly gas fills the lung. In the pressure support mode, gas delivery is terminated when the flow decays to approximately 25% of the peak flow.[10]

Modifying the flow pattern to accommodate the characteristics of the patient can reduce the work of breathing.[11] Figure 3 illustrates two pressure and flow patterns. The first two breaths of the sequence are pressure-supported breaths, whereas the last breath is a machine breath delivered in a decelerating flow pattern. Pressure during pressure-supported breaths rises primarily in response to the patient's characteristics—flow demand and the compliance and resistance of the lung. During the machine breath, the pressure ramp suggests a slow rise (concave or 'scooped' in appearance) illustrating that gas delivery is lagging behind patient demand. Current ventilators can now allow patient-related flow characteristics to modify breaths that have guaranteed volume.

TECHNOLOGY USED IN CURRENT VENTILATORS

New technologies have increased our ability to sense patient-related effort and to provide gas delivery in flow patterns that more nearly satisfy patient demand.

Increased Use of Microprocessors

Microprocessors are used within ventilators to perform a variety of simultaneous functions. Key among these functions is the provision of timing components of the ventilator. Microprocessors lend themselves to accurately determining blocks of time; thus machine, or controlled, breaths delivered by current generation ventilators are predominantly time-cycled.[12]

In addition, the microprocessors monitor signals from other components, such as pressure transducers and flow-delivery and exhalation valves. For example, the microprocessor might monitor mechanical movement of the valve, compare pressure inside the exhalation diaphragm with control panel settings, and process pressure signals in the circuit proximal to the valve.

Microprocessors can provide checks and balances by monitoring component tolerances. For example, the microprocessor can compare the pressure measurements between ventilator

outflow and pressure in the patient's proximal airway. This feedback can be used to help control the flow valve and supply gas in accordance with patient demand.

Microprocessors also perform complex computations and allow the ventilator to function according to intrinsic algorithms. For example, the logic that terminates flow during a pressure-supported breath is controlled by an algorithm that allows flow to decelerate to a predetermined point before the ventilator cycles into exhalation. Figure 3 illustrates termination at 25% of the peak flow.

Flow Valves

Current-generation ventilators use flow-control valves (gas-delivery valves) that are easily manipulated by microprocessor signals. Such flow-control valves include stepper motors, magnetic proportioning solenoids, and sequentially stacked digital solenoids. Each of these valves has inherent physical characteristics, including response time and maximum flow capabilities, that affect patient WOB. The relative benefits of one valving system over another is under investigation; however in general, the newer valves under microprocessor control are more sensitive to patient demand and offer improved flow characteristics in comparison to previous models.[11]

Flow Sensors

Three types of flow sensors are in current use: differential pressure transducers, variable-orifice pressure transducers, and heated wire anemometers.[13] Although called flow sensors, such devices actually measure or sense other variables—pressure in the case of pressure pneumotachometers and microamperage in heated wire anemometers. These signals are then converted and displayed as flow and volume.

The three sites for flow measurement are (1) inside the machine—a measurement of ventilator output; (2) at the patient-Y of the circuit, adding the capability of measuring inspiratory and expiratory flow and volume;[14,15] and (3) at the exhalation valve.

The flow sensor inside the ventilator measures the output from the ventilator to ensure that the ventilator is delivering the volume of gas that has been selected by the operator. These flow devices are, in general, permanent components within the ventilator—usually fixed-resistance differential-pressure transducers.

Flow measured at the patient-Y reflects the pattern and volume of gas actually delivered to the threshold of the patient's airway. This volume differs from the volume delivered by the ventilator because of compression and decompression of gas in the circuit tubing[8] or by any type of leak in the system. Devices located at the patient-Y allow flow measurement over a large range of flows and are often of the disposable variable-orifice type (eg, Ventrak, BiCore, Hamilton Veolar, Bird VIP).

Heated-wire anemometers are generally used to measure volume exiting the exhalation valve in adult systems. These measurements reflect the effects of tubing recoil or of volume decompression (Fig. 7). (Use of the heated-wire device at this site reduces water condensation, allows the device to be electrically isolated from the patient, and protects the sensitive wires from the hostile environment of the patient airway. In infant circuits, in which this is less of a concern, anemometers may be placed at the patient-Y, eg, Dräger Babylog and the Bear Cub.)

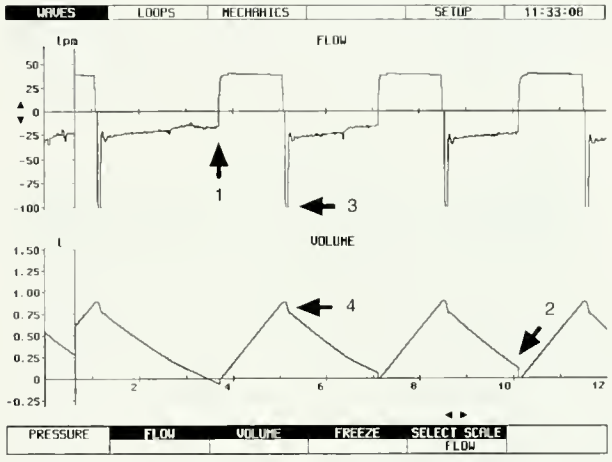

Fig. 7. Graph produced by ventilating the Michigan Instruments Test Lung using high airway resistance (R = 20 cm H_2O s L^{-1}). Note (1) the test lung does not fully empty prior to the beginning of the next breath (failure of the expiratory flow trace to return to zero) (Arrow 1) and results in air trapping in the test lung; (2) air trapping can also be observed through failure of the expiratory volume trace to return to zero (Arrow 2). (The volume collects during Breaths 2, 3, & 4, 'stacking' and then 'overshooting' on the following breath), and (3) as a result of the increased resistance located at the Y, a large amount of gas is compressed in the tubing. The sharp negative deflection in the expiratory flow trace signals gas decompression (Arrow 3), followed by the slower gas exiting the test lung. The volume of compressed gas can be estimated by noting the sharp dip in the volume trace (Arrow 4) coincident with the flow dip.

Triggering Mechanisms

Triggering mechanisms are based on two designs: pressure transducers that detect pressure swings below baseline and flow transducers that measure changes in flow.

Triggering mechanisms that incorporate pressure transducers measure pressure either proximal to the patient airway or internal to the ventilator. Proximal airway pressure sensing is more sensitive in detecting patient effort because the resistance offered by tubing components is avoided. The sensitivity of the ventilator is set based on the magnitude of pressure drop below baseline pressure or below PEEP. The signal from the transducer is read by the microprocessor, which in turn activates the flow-control valve.

Flow-triggering can be achieved by (1) use of a flow transducer in the airway (ie, the patient's drawing gas through the sensor triggers the flow-control valve to open) or (2) by the ventilator's providing a constant source of flow past the patient-Y and sensing flow at two points—one proximal to the patient-Y, the other distal to the patient Y or close to the exhalation valve. When the patient draws gas from the circuit, the ventilator senses a difference between the flows measured at the two points.

Investigators have claimed that flow-triggering requires less work to initiate delivery of a breath;[6,16] however, all flow-triggering systems, as a result of their inherent design, provide flow slightly in excess of the patient demand, resulting in a small, but continuous amount of pressure support.

Graphic Displays

Graphic displays on mechanical ventilators have been classified by ventilator engineers: (1) Scalar denotes the specific waveform generated by plotting one of the three primary ventilator variables against time (ie, pressure vs time, flow vs time, and volume vs time)[17] (Figs. 1,3,8). This terminology has been adopted to facilitate the selection of this group of variables on the monitoring device and for distinguishing variables plotted versus time from other types of graphs.[17] (2) Loop—denotes the simultaneous display of two variables plotted on x-y coordinates. The two most common loops are pressure-volume loops and flow-volume loops[15] (Figs. 9 & 10). Again, the term loop has been adapted as an indexing term for ease of selection on the monitoring packages and was historically used to refer to the flow-volume loop commonly described in the pulmonary function literature. Although loops have been analyzed for years by researchers in independent laboratories evaluating the mechanics of ventilation, the capability of evaluating lung mechanics at the bedside is a much more recent trend, primarily a result of the advent of microprocessor-driven ventilators.[16,19]

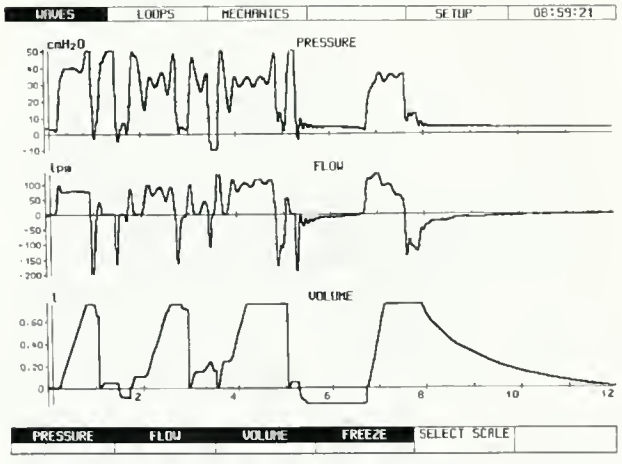

Fig. 8. 'Fighting' the ventilator: Large oscillations in pressure and flow trace are seen in response to repeated patient efforts.

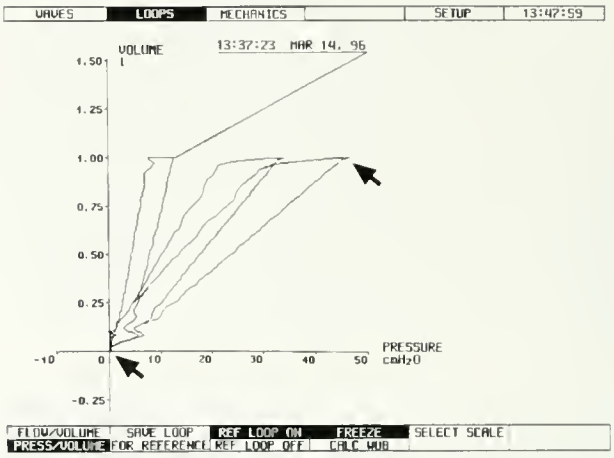

Fig. 9. Dynamic compliance is calculated by determining the slope of the line connecting the two points of zero flow—end inspiration (right arrow) and end expiration (left arrow). The compliance setting on the test lung was increased from C = 0.03 L/cm H_2O right-hand or darker curve to C = 0.1 L/H_2O left-hand curve.

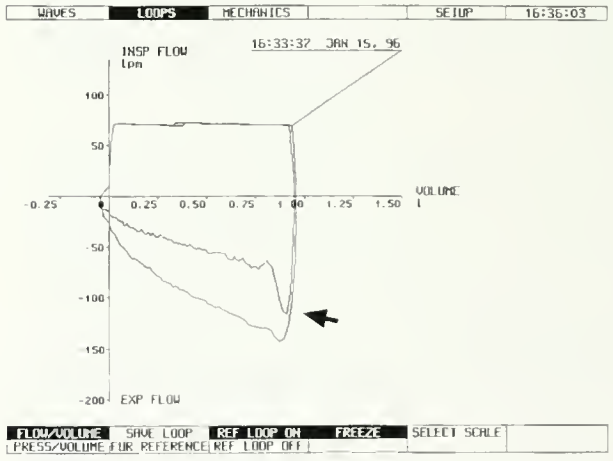

Fig. 10. Two flow-volume loops are illustrated, one from a lung with a high resistance (inner loop) and one with relatively low resistance (outer loop). Endotracheal tubes that limit or retard expiratory flow produce flow-volume patterns characteristic of the inner loop. The higher resistance of the inner loop reduces the slope of the exhalation portion of the curve. The high flow peak in the lower right hand corner (arrow) results from gas decompression in the tubing.

Using Graphics To Make Clinical Decisions

Graphic analysis is used for management of the patient on mechanical ventilation and may be applied: (1) for monitoring the function of the ventilator, (2) for evaluating the patient's response to mechanical ventilation, and (3) for making ventilator adjustments based on patient feedback.[20]

Scalars

Many current ventilators come equipped with viewing screens that display one or more scalars—pressure, flow, or volume graphed with respect to time. These may be independently viewed (Fig. 11) or all viewed on the same screen (Fig. 1).

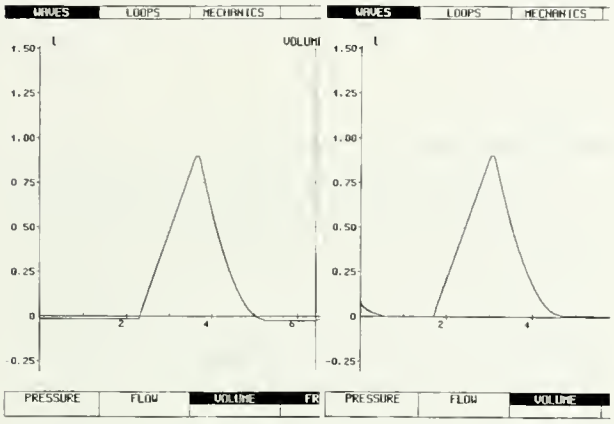

Fig. 11. The flow transducers can be calibrated internally and results observed by monitoring the resulting integration with time as volume traces. These two traces actually represent the return to normal function following a 20-minute warm-up period (internal flow sensor-inspiratory volume, matches external flow sensor-expiratory volume. In addition, the trace displays a single scalar and illustrates the increased resolution obtained when the vertical scale or amplitude (sizing) is increased. Compare to Figure 12.

Options allow adjustment of the viewing screen: (1) Sweep speed may be altered to increase or decrease the number of breaths displayed; faster sweep speeds magnify the horizontal scale and are advantageous for evaluating or adjusting individual variables on the ventilator, such as pressure or flow (Fig. 3); slower sweep speeds allow the viewer to capture more breaths on the screen and may be used to make serial adjustments in machine settings when it is desirable to view or compare the gradual changes resulting from the adjustment (Fig. 12). (2) Sizing or amplitude may be adjusted to allow viewing of a variable in finer detail (Fig. 11). It is important for clinicians to systematically evaluate each of the scalars at maximum amplitude to avoid missing changes that can cause problems.

We believe that the information obtained from viewing scalars provides an entirely new dimension for solving problems related to the patient and ventilator interface. Such displays have greatly increased the clinician's ability to more appropriately adjust the ventilator to meet the demands of the patient. This is particularly important in evaluating conditions in which patient effort or WOB has increased as a result of patient-ventilator dyssynchrony stemming from inadequate sensitivity or inadequate inspiratory gas flow, or the need for therapeutic intervention to remove secretions or reduce bronchospasm.

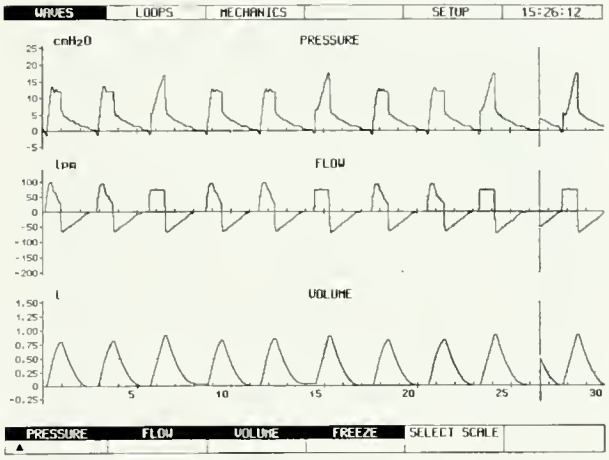

Fig. 12. Some manufacturers offer display options. This trace illustrates a change in the sweep speed or horizontal time scale to include a larger time frame. Observations of the results of individual machine adjustments can be tracked and compared to the breaths displayed preceding the change.

The Pressure Waveform

From a clinical decision standpoint, the variable that provides the most information related to the patient's interaction with the ventilator is the pressure waveform.[15] Information available from the pressure-time trace includes:

Synchrony. The absence of patient-ventilator synchrony (ie, dyssynchrony) is manifested on the pressure trace as inspiratory or expiratory efforts that occur during the gas delivery phase of the ventilator. (1) Patient attempts to exhale during the inspiratory phase result in higher than normal peak inspiratory pressures, and attempts to inhale during the delivery of the breaths appear as drops in pressure (Fig. 3). Multiple spontaneous breaths attempted during the delivery of a positive-pressure breath show up as a ragged variation in the pressure trace and as an uneven flow trace (Fig. 8). (2) Peak inspiratory pressure varies on a breath-to-breath basis during volume-limited ventilation. If the patient is relaxed and the patient and ventilator are functioning in synchrony, the pressure trace should appear smooth, and the waveform should repeat itself. Large differences or variations in pressure indicate dyssynchrony.

Sensitivity. Many ventilators provide a sensitivity adjustment that alters the amount of pressure that must be generated by the patient in order to trigger the delivery of a breath. Fine tuning of the sensitivity is necessary because the patient's neural drive to breath may change during recovery. Under light sedation, the patient may require that the triggering mecha-

nism be relatively sensitive. Once the patient is fully awake, this may no longer be needed, and other factors (such as patient movement) may inadvertently trigger the ventilator. The addition of PEEP, depending on the ventilator design, may require slight alterations in the trigger sensitivity.

When sensitivity is set correctly, pressures should not drop more than 1-2 cm below baseline during the initiation of a machine breath or during spontaneous breathing efforts.[7,21] Larger pressure oscillations represent increased work for the patient and indicate that the machine is not triggering easily enough or that the patient is demanding gas flow in excess of what the machine is supplying[22] (Fig. 2). (1) The pressure trace can be used to evaluate the amount of patient effort required to initiate ventilation. Differences in effort are indicated by changes in the magnitude and the slope of the inspiratory pressure trace (Fig. 2). (2) The pressure trace may also be used to evaluate whether the sensitivity setting in the SIMV mode is adequate. For example, if the SIMV rate is set ≤ 4 and no pressure-supported breaths are apparent on the trace, the patient may be receiving only mechanical breaths because spontaneous breath efforts are failing to activate the flow valve.

Peak Flow. When peak inspiratory flow during volume-targeted ventilation is set appropriately, the airway pressure trace should appear as a pressure ramp or be slightly convex during normal passive inflation. When the patient is demanding gas flow in excess of what the ventilator provides, the pressure trace may have a 'scooped out' appearance [7,20] (concave pattern, Fig. 13A), and the inspiratory flow setting should be increased. Figure 13A illustrates a sequence in which the initial peak flow setting is too low and the sensitivity setting requires the patient to generate excessive inspiratory pressure in order to trigger the ventilator. The square-flow machine breath has a lower peak flow than the patient-instigated breath, which is corrected late in the sequence by increasing the peak flow setting. As a consequence of increased sensitivity, gas flow is seen to commence much closer to the initiation of patient effort in the later breaths (Fig. 13A & 13B).

Calculation of Compliance & Resistance. Current ventilators incorporate a timing option for machine breaths that allows the addition of a plateau or pause at the end of inspiration. During this pause the exhalation valve is closed, and gas is held in the lung. The plateau pressure measured during this pause may be used for the calculation of system compliance[2] (C) (Fig. 14).

$$C = \frac{V_T}{P_{plat} - P_{end\text{-}e}}, \qquad \text{[Equation 1]}$$

where C = system compliance, P_{plat} = plateau pressure, and $P_{end\text{-}e}$ = end-expiratory pressure.

The peak pressure immediately prior to the plateau is the result of (1) the static inflation pressure—the pressure required to stretch the elastic components of the lung and chest wall to full inflation, and (2) the pressure needed to generate gas flow through the composite tubing system—the ventilator tub-

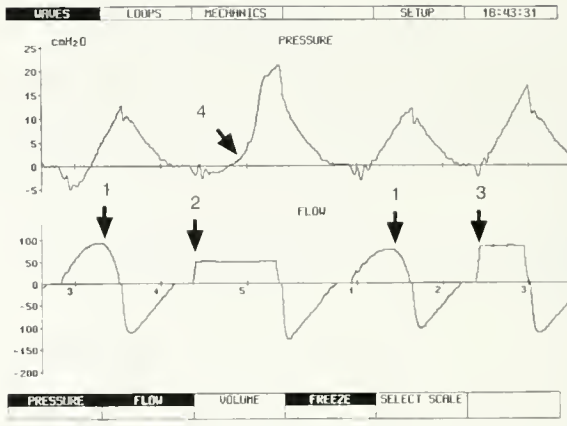

Fig. 13A. Adjustment of peak-flow setting: During the first two breaths the sensitivity setting is set inappropriately causing a delay in the delivery of the breath and requiring excessive patient effort. The second breath is a machine breath that illustrates an inappropriate peak flow. The ventilator peak flow (Arrow 2) is set < the flow generated during the initial patient-oriented pressure-supported breath (Arrow 1). The inadequate flow setting results in a concave, or dished out, pressure trace (Arrow 4). During the last breath (Arrow 3), the machine flow setting has been increased to mimic patient demand. In addition, the sensitivity has been changed improving the timing of gas flow with patient effort.

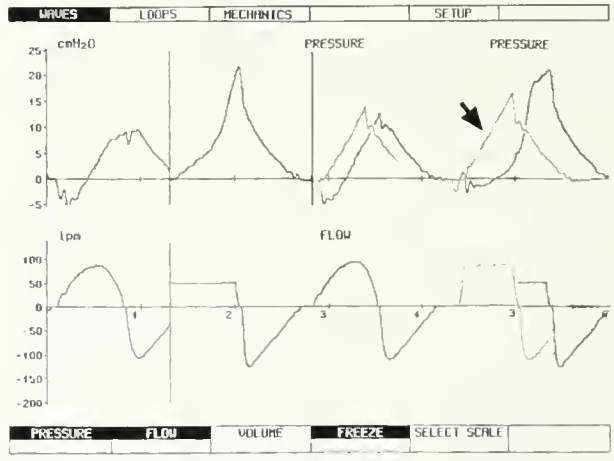

Fig. 13B. Concave or 'scooped' pressure trace: This overlay illustrates more clearly the changes in gas delivery resulting from adjusting peak flow and sensitivity settings on the ventilator. The corrected pressure and flow traces have been superimposed on 13A (arrows indicate overlaid breaths). Note the important difference: (1) the corrected breath is delivered much more quickly, and (2) the concave appearance of the square-flow machine breath has been corrected by increasing the peak flow setting. The corrected settings reduce the amount of patient work. The extra work performed by the patient during the uncorrected condition is represented by the area between the two pressure traces.

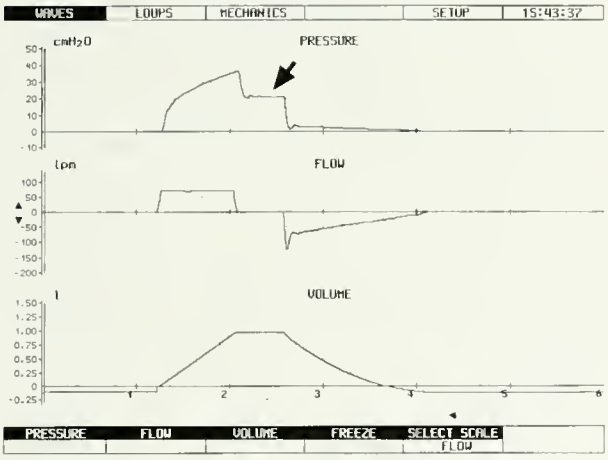

Fig. 14. Plateau pressure and splicing of flow trace: A time delay or inspiratory hold has been added to the machine breath and is seen as a pressure plateau in the pressure trace arrow and as a portion of zero flow in the flow trace. The pause removes any pressure resulting from resistance to gas flow in the lung or circuit and results in a static recoil pressure plateau. The information from the inspiratory flow sensor has been spliced with the signal from the expiratory flow transducer so that the volume trace remains continuous.

ing, endotracheal tube, and the patient airways.[23] Subtracting the plateau pressure from the peak inflation pressure quantitates the pressure necessary to generate gas flow and overcome airflow resistance.[2]

$$R_I = \frac{P_{peak} - P_{plat}}{\dot{V}_I}, \qquad \text{[Equation 2]}$$

where R_I = inspiratory resistance, P_{peak} = peak inspiratory pressure, and $\dot{V}_I$ = inspiratory flow.

$$R_E = \frac{P_{peak} - P_{end\text{-}e}}{\dot{V}_E}, \qquad \text{[Equation 3]}$$

where R_E = expiratory resistance, $\dot{V}_E$ = flow at onset of expiration.

Serial measurements of compliance and resistance are useful for tracking the progression of many pulmonary conditions. Decreases in system compliance may indicate the development of atelectasis, consolidation, pneumonia, or the development of acute respiratory distress syndrome (ARDS).[24] Increases in compliance suggest expansion of an atelectatic area, resolution of consolidation, decompression of pneumothorax, or reversal of ARDS.[20] Increases in pulmonary resistance results from decreases in the diameter of the airway lumen as a result of edema, partial airway obstruction, or bronchospasm, and may indicate the need for sympathomimetics or bronchial hygiene therapy.[20] In addition, condensation and accumulation of secretions in the tubing adds resistance and needs to be monitored and cleared on a regular basis.

Work. Work performed by the ventilator can be estimated from the magnitude of the pressure trace during volume-targeted passive inflation (mandatory machine breaths). Although the actual work to inflate the lung can be determined from other traces, inflation pressures are rough estimates of the work performed by the ventilator and also reflect changes in lung pathology (eg, decreasing compliance as in the development of ARDS). Although the actual work performed by the ventilator is of little concern to the clinician, weighing machine work against the work that the patient must assume during the weaning process is important.

Setting Pressure Support. The pressure trace may be used to adjust the target pressure during pressure support ventilation. In this mode, the ventilator augments the patient-initiated breath with a pressure boost. As the pressure setting is increased, the pressure trace can be monitored for the specific characteristics of a pressure-supported breath—a nearly square pressure waveform (Figs. 3 & 4).

Determining Auto-PEEP. Auto-PEEP is the pressure exerted at end-exhalation that results from incomplete emptying of the lung (also called intrinsic or occult PEEP).[20,25,26] Some microprocessors are programmed to close the exhalation valve immediately prior to the onset of the next mechanical breath for measurement of auto-PEEP. Auto-PEEP is then determined by viewing the pressure trace during the end-expiratory hold (Fig. 15).

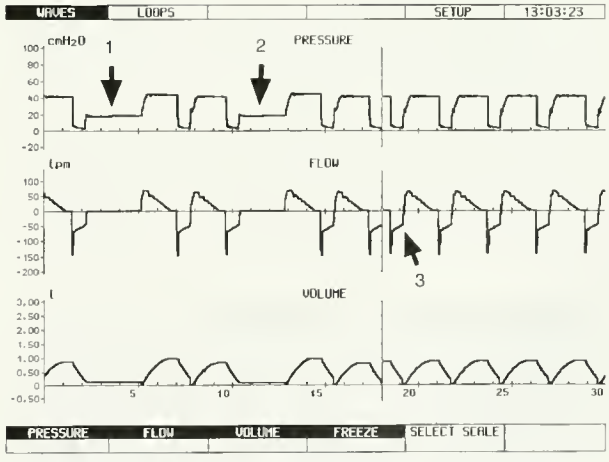

Fig. 15. Early in this sequence auto-PEEP was determined by delaying the delivery of the machine breath and closing the exhalation valve immediately prior to what would have been the next machine breath. If gas under pressure remains in the lung, a pressure plateau (Arrows 1 & 2) appears and the magnitude of the pressure plateau is a measure of auto-PEEP. Latter in the sequence, auto-PEEP can still be identified by failure of the expiratory flow trace to return to zero (Arrow 3), indicating that gas is still trying to exit the lung.

Evaluating Exhalation Valve Function. Malfunction of the exhalation valve should be suspected if the pressure trace fails to achieve a true plateau during inspiratory hold or if the trace indicates that PEEP is not maintained or is bled off toward zero at end-exhalation.

The Flow Waveform

Background & Assuring Proper Transducer Function. The flow waveform can provide unique monitoring information when used alone or in conjunction with the pressure trace. The flow setting is perhaps the most frequently inappropriately set ventilator variable.[15] Although we now have an objective method for adjusting flow, many clinicians still lack experience in flow monitoring. The flow trace has both inspiratory and expiratory components, and, as noted earlier, there are three possible sites for placement of the flow sensors. The flow graphic on many ventilators is the result of splicing the inspiratory flow curve (measured by the flow sensor inside the machine) to the expiratory flow curve (measured by the sensor at the exhalation valve). This splicing allows for separate evaluation of the flow transducers (Figs. 14 & 16). If one of the transducers is malfunctioning, only half of the flow trace appears (Fig. 16). In our experience, it is usually the external flow transducer that is more susceptible to failure because of its design and location.

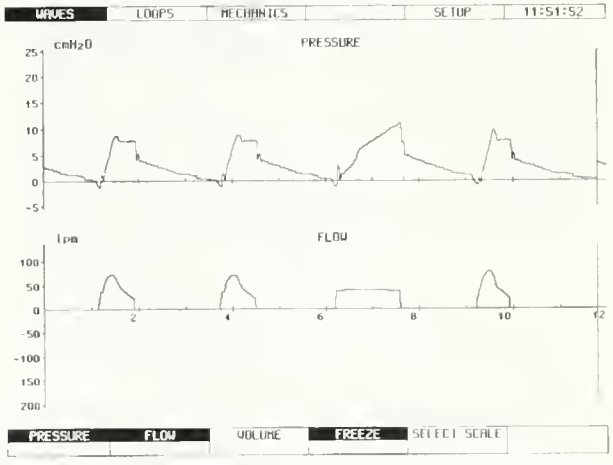

Fig. 16. The expiratory flow curve is missing from the trace indicating that the external flow transducer has malfunctioned. In addition, the peak flow setting during the square-flow breath is set below the peak flow observed during the previous patient-oriented pressure-supported breaths. As a result the pressure trace is 'scooped' or concave. This can be corrected by increasing the machine flow setting.

Using the Inspiratory Flow Graphic. (1) Clinicians need to determine whether the flow pattern that is being delivered to the patient reflects the flow pattern that was selected on the ventilator and whether the pattern has the characteristics desired under the particular mode of ventilation selected (eg, under pressure support does the flow pattern decelerate to 25% of peak flow as in Figure 3, or under pressure control does the flow decay to zero just prior to the end of the breath as in Figure 15?). Many current ventilators offer flow options that allow selection of one of three flow patterns: square, decelerating, or sinusoidal (Fig. 17). Under many circumstances, varying inspiratory flow waveforms appear to have little clinical effect,[27,28] so long as flow adequately meets patient demand. However, the peak flow setting frequently may be inadequate. (Settings of at least 80 L/min are recommended).[15] In some cases, patients with increased airways resistance seem to have better gas exchange with decelerating waveforms,[29] or as an alternative the same improvement in gas exchange may be achieved with inflation holds and lengthened inspiratory times.[30] Normal inspiratory times are slightly < 1 second. Increases in inspiratory time can result in hemodynamic embarrassment (ie, decreasing venous return) and increases in total cycle time can lead to air trapping. (2) Is the ventilator flow-valve setting appropriate? Some ventilators (eg, Bear 1000, Siemens Servo 300, Hamilton Veolar) have mechanisms that have the ability to control the responsiveness of the flow valve[16,31](Fig. 18). This mechanism controls how rapidly or slowly the valve opens, thus influencing the rate at which gas is initially supplied to the patient. This mimics the differences in flow pattern or flow demand during exercise or during times of heightened respiratory drive.

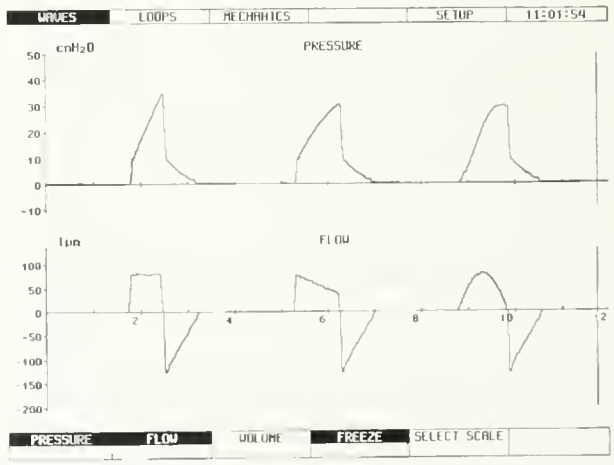

Fig. 17. The three standard mechanical ventilator flow patterns: square, decelerating, and sinusoidal. The effect of flow pattern on the development of pressure in the circuit is also displayed.

Using the Expiratory Flow Graphic. Identification of auto-PEEP: (1) Although the pressure trace can be used to determine the magnitude of auto-PEEP once its presence is known, the flow trace can be used independently (without activation

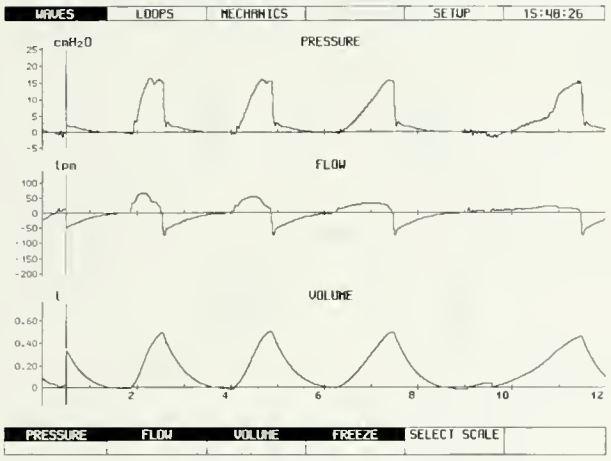

Fig. 18. Changes in the gas delivery system produced by adjusting the "pressure slope" function. The sloping function controls that rate at which the flow valve opens. Four different slope settings are illustrated (–2, –4, –6, –8). During the first breath, the flow valve is delivering flow adequate for patient demand; the pressure ramp rises and is linear in appearance; (2) during the third and fourth breaths the flow valve opens too slowly to meet patient demand, resulting in a convex pressure trace (inadequate patient flow) and a prolonged inspiratory time.

of the exhalation hold) by observing that the flow trace does not decay to zero at the end of exhalation (Figs. 7 & 15). (2) In evaluation of the expiratory flow pattern, both the time required for the flow trace to decay to zero and the actual flow pattern are helpful in monitoring patient response. Prolonged exhalations may be caused by bronchospasm, which can be treated with bronchodilator drugs, or by airway compression associated with obstructive lung disease. Interruptions in the flow trace (ie, jaggedness) are commonly caused by secretions or by the existence of 1-way flap valves (eg, mucus plugs or tissue flaps caused by traumatic intubation). (3) The shape of the curve, the peak expiratory flow, and the length of time it takes the expiratory flow curve to return to zero can be used to assess the effectiveness of bronchodilator therapy;[32] effective bronchodilator therapy should decrease the time to return to zero and increase the peak expiratory flow (Fig. 19).[33]

Pressure & Flow Waveforms in Combination

Optimizing the Patient Flow Pattern. The adequacy of airflow should be evaluated in all ventilator modes. The peak flow should be adjusted to ensure that the machine meets the patient's demand (Fig. 13B). The peak flow should be adjusted until the pressure trace shows a sharp rise and is not concave in appearance.

Determining Expiratory Resistance. The calculation of resistance requires simultaneous measurements from the pressure and flow traces (see Equation 1).

Adjusting Inspiratory Time in the Pressure Control Mode. Inspiratory flow should fall to zero as the pressure plateau is reached (Fig. 15). In addition under some circumstances, prolongation of the inspiratory time or inflation hold may be desirable (eg, to improve oxygenation in ARDS patients[34]).

The Volume Waveform

The volume waveform is used to help evaluate the patient's ventilatory status. By evaluating the magnitude of the spontaneous breaths, the clinician can determine whether the patient's ventilatory status has improved, suggesting readiness for weaning or the need for additional ventilation.

Quantifying Air Leak & Calibrating Flow Transducers. Air leaks may be identified by noting the volume differences between the inspiratory and expiratory volume traces (Fig. 20). Volume measurement can also be used to verify correct function and calibration of the flow transducers (Fig. 11). The volume traces are derived by integration of the flow measurements from both inspiratory and expiratory flow transducers. Discrepancies are indicated by absence of one of the traces or by failure of one of the traces to return to zero (either under- or overshooting the zero mark). Unequal volume traces commonly indicate the need to recalibrate the flow transducer or correct the barometric pressure setting within the machine.

Evaluating Spontaneous Ventilation Capabilities. Periodic measurement of spontaneous tidal volume, breathing frequency, and pulmonary mechanics is necessary to track the status of the pulmonary system and to determine whether ventilatory support should be increased, decreased, or discontinued.[35] Increased spontaneous volumes may be the first indication that the patient is capable of assuming a greater role in ventilation, whereas decreased volumes and increased rates indicate the need to increase ventilatory support. One method of increasing ventilation is to provide pressure support to spontaneous breaths. If a specific volume is desired, the pressure trace may be used to monitor changes in the delivered volume as the pressure support is adjusted (Fig. 4).

Determining the Rapid Shallow Breathing Index (f/V_T). It is important to assess the ventilatory pattern when determining the degree of ventilatory dysfunction and readiness for weaning. Increases in breathing frequency suggest declining ventilatory function and decreases in tidal volume (V_T) while less predictive may suggest that the patient is not ready for weaning. When used in combination (f/V_T), the index provides a relatively strong indicator of weaning success.[36]

When ventilatory function is noted to be improving, as indicated by an increase in V_T, a decrease in ventilatory support may be indicated: (1) decreasing the set pressure level in pressure control ventilation, (2) decreasing the SIMV rate, or (3) beginning other aspects of weaning, such as a change

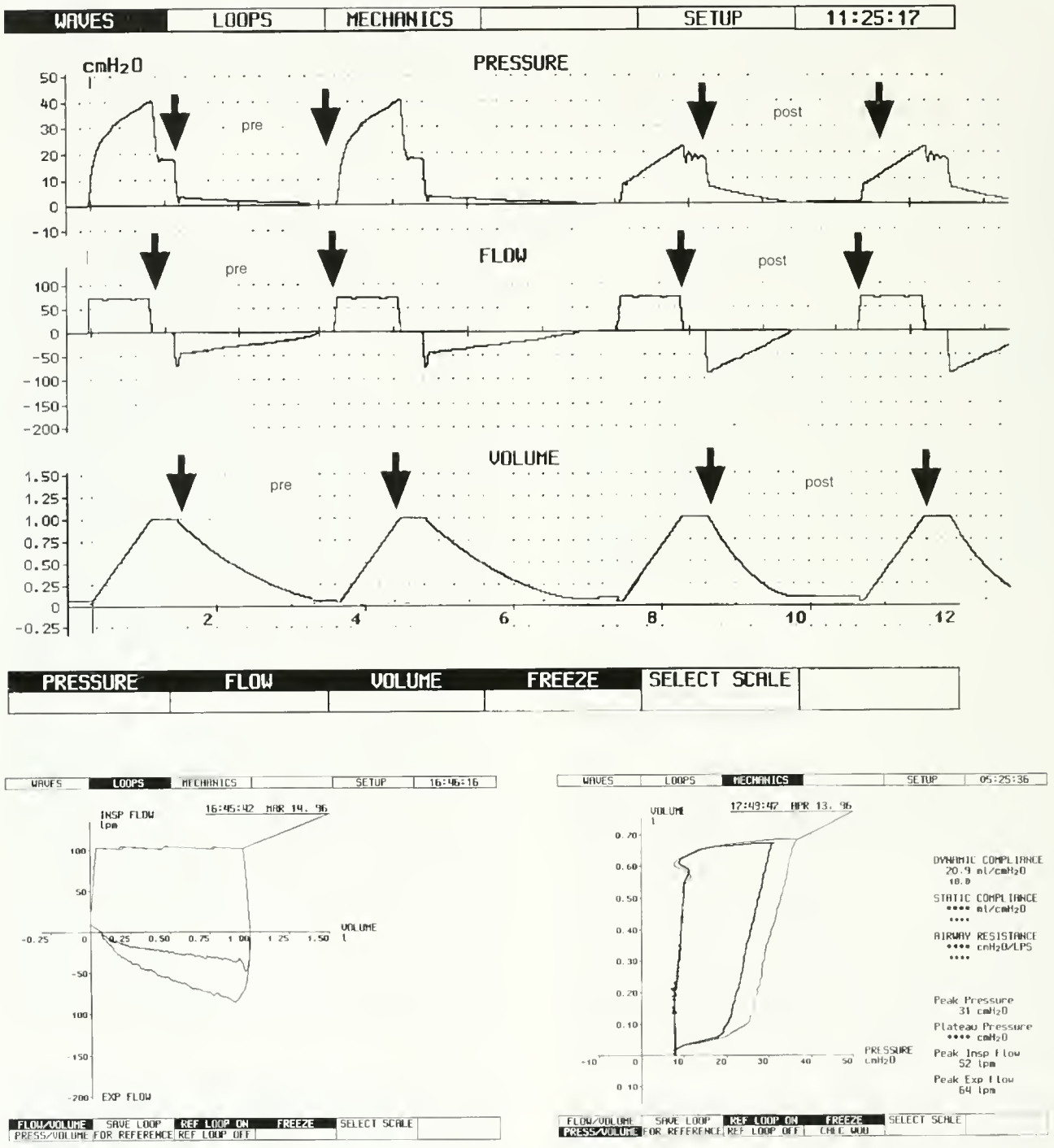

Fig. 19. Changes that may be observed following bronchodilator therapy: (1) scalars, (2) flow-volume loop, and (3) pressure-volume loop—labeled with postbronchodilator condition (lower airway resistance). Scalar Graphic: traces indicate differences following the removal of the high-resistance condition [created on TTL test lung using R = 20, R = 5, C = 0.03; Flow = 70 L/min] (a) pressure trace—reduction in the peak minus plateau pressure difference, (b) peak flow increased during expiration, and the expiratory flow profile changed (increased slope); complete exhalation occurs over a shorter time interval (postcondition), (c) slope of the volume trace during exhalation increases indicating quicker exhalation. Flow-volume loop: removal of the high resistance (R = 20) results in greater peak flow during exhalation and a change in the expiratory profile—steeper slope (the graphic turned upside down represents the pulmonary function flow-volume loop). (Inner loop is the precondition; the outer loop, postcondition.) Pressure-volume loop: The outer loop, from an asthma patient initially seen in the emergency department, represents the pretreatment condition. The inner loop represents the post-bronchodilator condition, where treatment successfully reduced the airflow resistance and narrowed the width of the dynamic loop.

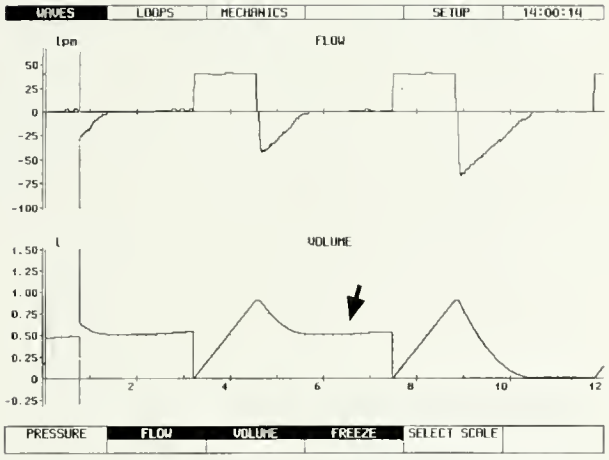

Fig. 20. The graph illustrates a leak in the system or loss of volume. The right half of the volume trace (the expiratory volume) does not return to zero (arrow).

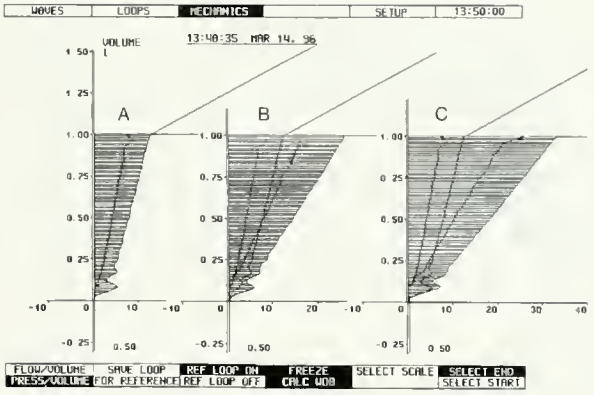

Fig. 21. Work of breathing is determined by measuring the area of the pressure-volume curve bounded on the right by the inspiratory curve, on the left by the volume axis or level of positive end-expiratory pressure (PEEP), and at the top by the maximum inspiratory volume. The three graphs were created by changing the compliance setting on the test lung. A. C_{lung} = 0.05 L/cm H_2O; B. C_{lung} = 0.02 L/cm H_2O; C. C_{lung} = 0.015 L/cm H_2O. Changes in work performed by the ventilator are the result of increased lung elasticity. V_T = 1.0 L; peak flow = 70 L/min; pressure slope = –5, with no external resistance added.

in mode, a decrease in extrinsic PEEP, or changes in oxygen concentration.

Loops

Pressure-Volume Loops

The simultaneous display of pressure plotted against volume provides information about lung mechanics that is useful both in monitoring and in ventilator adjustment: determination of maximum V_T setting, evaluation of resistance and response to bronchodilators, measurement and evaluation of WOB and work to trigger the ventilator or patient demand valve.

Work of Breathing. Work as applied to pulmonary mechanics is the product of pressure and volume. When volume and pressure are displayed on x-y coordinates, work is represented by the area of the loop (Fig. 21).[37,38] This work may be performed either by the ventilator (ie, a positive pressure breath) or by the patient (spontaneous breath).[20] Pressure is usually measured in the ventilator circuit (airway pressure). For spontaneous breaths, this means that the area of the loop represents work imposed by the ventilator system and does not include work required to overcome the resistance of the artificial airway or the intrinsic properties of the lung.[20] Estimation of patient work to overcome airway resistance and to inflate the lung requires placement of an esophageal balloon and uses esophageal pressure as an approximation of pleural pressure.

For positive pressure breaths, the loop gives information about the work required to stretch the elastic components of the respiratory system (lung and thorax, Fig. 9) and to overcome resistance or nonelastic work (airflow resistance, tissue viscous resistance, inertia, and the resistance of the connecting tubing and endotracheal tube, Fig. 22). The work performed during inspiration to stretch the lung is then stored as potential energy that can be used during exhalation to overcome the expiratory resistance.

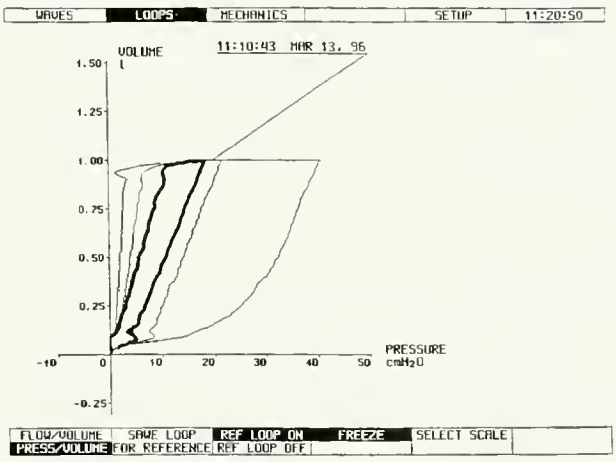

Fig. 22. Changes in resistance are reflected as changes in the width of the pressure-volume loop. Each loop was recorded from a test lung with a constant compliance setting; C = 0.02L, but with the resistance varying from a high setting (R = 20, wide loop) to a low setting (R = 0, narrow enhanced loop). The increase in the width of the outer loop represents an increase in inspiratory resistance (to the right) and expiratory resistance (to the left).

Dynamic Compliance. Dynamic compliance differs from the static measurements described under Scalars that are achieved

with addition of an inspiratory hold. Dynamic compliance can be determined from the information provided on the pressure-volume loop by measuring the slope of the line connecting the two points of flow reversal (ie, zero flow at the airway). Shifts of the pressure-volume curve to the right indicate a decrease in dynamic compliance whereas shifts to the left indicate increases in dynamic compliance (Fig. 9). The dynamic measurement includes both the elastic and resistive characteristics of the system, whereas the static compliance measurement excludes any of the flow-resistance properties.

Lung Overdistention. Respiratory system overdistention is characterized on the pressure-volume curve by a volume plateau or flattened portion of the inspiratory curve at end-inspiration (so-called overdistention beak, Fig. 23).

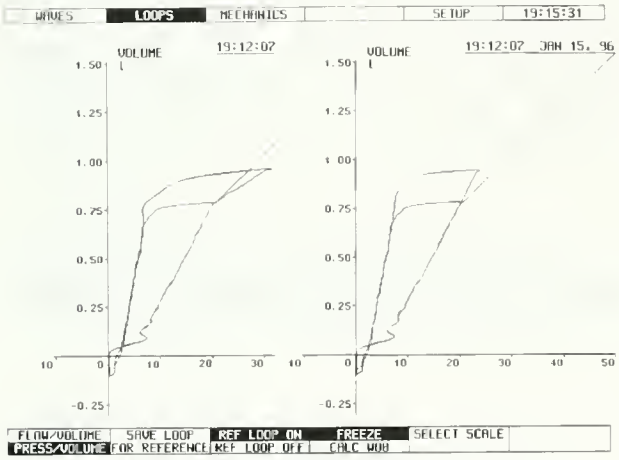

Fig. 23. A. Addition of volume to the lung results in a relatively small increase in peak pressure. B. Addition of volume to an already distended lung causes a sharp increase in peak pressure (pressure beak)—representing overdistention of the elastic component of the lung.

Trigger Sensitivity. The patient effort required to trigger the ventilator may be evaluated by observing the magnitude of the small loop on the volume-pressure trace (Fig. 24).

Exhalation Valve Function. The same patient-effort loop noted under trigger sensitivity (small loop) can also be used to identify incompetent or malfunctioning exhalation valves. During patient inspiratory efforts, leaky or incompetent valves allow gas to enter through the flow sensor opposite the normal direction of gas flow. This results in a portion of the volume trace appearing as a negative loop (volume loop extends below the horizontal axis).

Pressure Support Settings. During SIMV with pressure support, the spontaneous breaths show up as concentric small loops within the larger machine breaths (Fig. 25). By observing the concentric loops, the level of pressure support can be adjusted to increase the size of patient breaths to match machine breaths (PSV_{max}).[20]

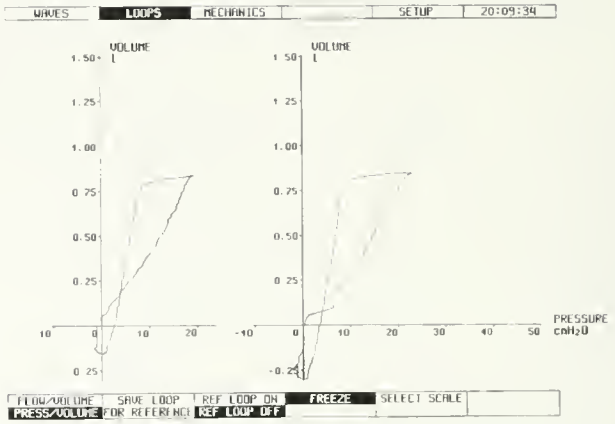

Fig. 24. Pressure-volume loops representing two different sensitivity settings on the ventilator. Areas at the lower portion of the loops (arrows) indicate the work required to trigger the ventilator, or initiate inspiration. The loop on the right represents more patient work.

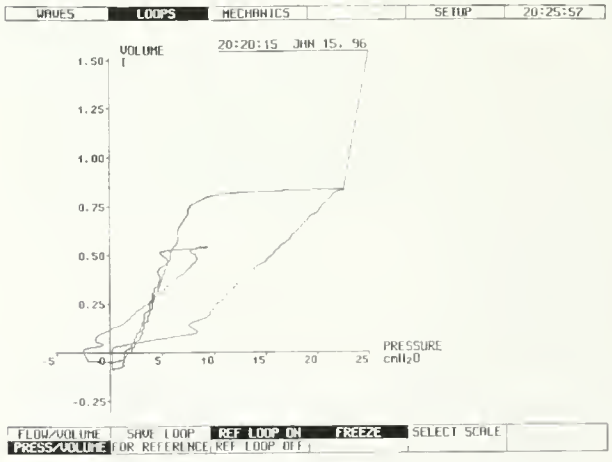

Fig. 25. The larger loop is the mandatory machine breath, the smaller loop is the pressure-supported breath. Changes in the size of the pressure-supported breath are easy to observe because the level of pressure is increased. The volume derived from the pressure increases as the pressure is titrated upwards.

Flow-Volume Loops

Flow-volume loops have long been displayed on pulmonary function testing equipment and recently have been added to the graphics packages of some newer ventilators. The viewing orientation, however, is slightly different because the y-axis is inverted to retain consistency with the scalar measurements,

which record inspiratory flow as positive, whereas with pulmonary function equipment the forced vital capacity is the primary spirometric maneuver and the expiratory flow is graphed as positive (ie, inspiratory flow is negative). Another difference is that flow-volume loops on mechanical ventilators generally represent only tidal breaths rather than vital capacity maneuvers. Flow-volume loops provide clinical information about bronchodilator therapy[39]—changes in peak flow or the shape of the expiratory flow curve and information related to the appropriate sizing of endotracheal or tracheostomy tubes.

Airway Resistance. The flow-volume loop may be useful in quantifying the effectiveness of bronchodilator therapy (Fig. 19) by observing changes in[40] (1) the contour of the expiratory loop (the loop should be less concave, and the expiratory flow at various times during exhalation should increase); (2) the peak expiratory flow (the flow should increase); (3) the expiratory time (time should decrease); and (4) spontaneous V_T (V_T may increase).

Expiratory Flows. If the endotracheal tube is sized appropriately, the expiratory curve should have a sharp rise and gradual fall (Fig. 10) and should not be square in appearance.[41]

USING RESPIRATORY MECHANICS IN WEANING

General Considerations

Measurement and tracking of pulmonary mechanics variables, such as compliance, resistance, WOB, and other indices that are helpful in evaluating the patient's weaning status, represent the most recent addition to ventilator monitoring capabilities and are also available in freestanding monitoring devices.

The subject of weaning indices and weaning techniques continues to be a topic of constant debate and scientific inquiry. To date no single method has been shown to be conclusively superior.[42] What is evident, however, is that successful weaning depends on treatment of the underlying pulmonary problem and conditioning of the ventilatory muscles. Muscle conditioning concepts that apply to striated muscles seem to apply equally well to the respiratory muscles,[43] including the fact that there are many different training concepts or theories. Different clinicians have used a variety of strategies in the development of ventilator management care plans[44] (eg, intermittent periods of spontaneous ventilation with the patient placed on a T-piece followed by periods of rest during which the patient is returned to the ventilator, gradual reduction in the amount of pressure support, or reduction of mandatory breaths under SIMV.[45,46]

Specific Measures

Although no single measurement is entirely indicative of successful weaning,[47] serial measurements and trend analysis of the variables to be discussed can be used to evaluate the patient's progress once a particular strategy has been selected. The objective data when considered collectively assist the clinician in making reasonable decisions about the patient's progress during the weaning trial.

Variables that provide information pertinent to the weaning process and provide indications of the patient's ability to wean can be categorized as (1) indicators of strength—measures of the patient's ability to take a deep breath (the vital capacity) and to generate a cough, and (2) indicators of endurance—measures of the patient's ability to maintain an adequate minute ventilation over an extended period of time. In addition, the monitors measure and record minute ventilation ($\dot{V}_E$), respiratory rate (RR, or f), and WOB.

Measures of Strength

Maximum Inspiratory Pressure (MIP). MIP is the pressure change, measured by esophageal balloon, that the patient can generate when the airway is occluded for several breaths (Fig. 26). Cooperative patients can perform the maneuver in a short period of time; however, many patients require longer occlusion periods in order for the neural drive to increase and produce a maximum effort. MIP is a reflection of diaphragmatic strength and may also be used to monitor respiratory muscle endurance when serial measurements are made.[48] MIP differs slightly from the more commonly used negative inspiratory force (NIF), which is measured at the mouth but also reflects or measures diaphragmatic strength.[48,49] The normal range for MIP is from −30 cm H_2O (low effort) to −140 cm H_2O (high effort) and MIP should be more negative than −20 cm H_2O before weaning is undertaken.[49,50]

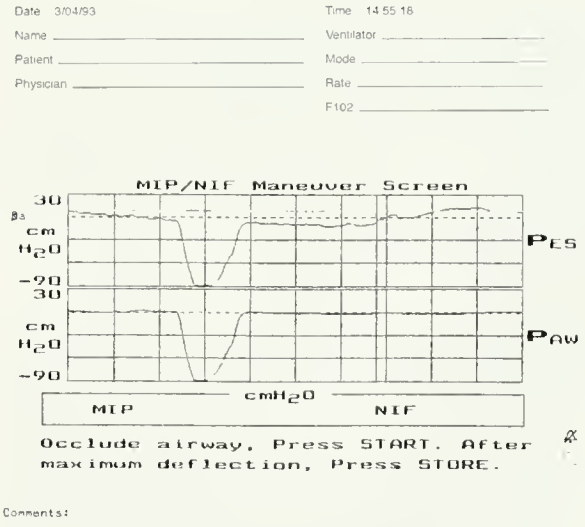

Fig. 26. The MIP/NIF maneuver. Pressure measurements are recorded from the airway and the esophageal balloon during an inspiratory effort against a closed airway. This case represents normal diaphragmatic strength.

Respiratory Drive ($P_{0.1}$ or P_{100}). This is a measurement of the esophageal pressure measured 100 milliseconds after the onset of a breath. The value is indicative of the amount of neural activity that is driving diaphragmatic movement (respiratory center drive). "Mouth occlusion pressure (P_{100}) has been shown to correlate with phrenic nerve activity and is thus considered to be a measure of central respiratory drive."[48] The normal range is 2-4 cm H_2O, and a $P_{0.1} < 6$ cm H_2O[7,51,52] is an indication of readiness for weaning.

Delta Esophageal Pressure, (ΔP_{es}). This value is measured as the total downward or negative deflection in the esophageal pressure trace during a patient-generated breath beginning from the end-resting esophageal pressure (measured in cm H_2O). It is an indication of the pressure generated by the patient in stretching the lung and in drawing gas into the lung. Although it has been described in the literature as a strength parameter, it also has endurance implications because of the work that must be performed with each patient breath. Normal range is 5-10 cm H_2O, and $\Delta P_{es} < 15$ cm H_2O is an indication of readiness for weaning.[53]

Measures of Endurance

Respiratory Time Fraction (T_I/T_{TOT}). The ratio of time spent during inspiration to total respiratory cycle time increases as the respiratory muscles fatigue (ie, the patient spends a larger percentage of the respiratory cycle in inspiratory activity).[54] Normal range is 0.3-0.5[55] but because of wide variability among subjects, no specific range indicates readiness for weaning. Once the baseline values have been established, serial changes can be used to monitor diaphragmatic function.

Pressure Time Product (PTP). The PTP is an estimate of the metabolic work performed by respiratory muscles over the entire breath.[56,57] It is measured as the integral of the esophageal pressure over time for the duration of the contraction of the respiratory muscles (Fig. 27). The normal range is 200 to 300 cm H_2O/s/min,[58] but great variability results from differences in patient size and strength. However, once a baseline has been established serial measurements can be used for monitoring.

Rapid shallow breathing index (f/V_T). This variable is relatively easy to record even without complex monitoring and appears to be a reasonably good indicator of respiratory muscle endurance or fatigue. As the respiratory muscles fatigue, V_T decreases and f increases. The importance of this relationship was described by Tobin et al[36,59] using inductive plethysmograph technology—a dual recording of chest-wall and abdominal motion from impedance bands wrapped around the thorax and the abdomen. Patients who fail weaning trials generally exhibit increases in f, decreases in V_T, and increases in P_{aCO_2} in spite of maintained or increased $\dot{V}_E$, and they develop asynchrony—a lag between the chest-wall and abdominal wall motion. Frequency-tidal volume indexes of < 100 indicate that the patient is ready for weaning and predict successful trials.[36,59] The normal range is 60-90 and values ≥ 105. Values above 105 suggest that the patient still needs ventilatory assistance.[36]

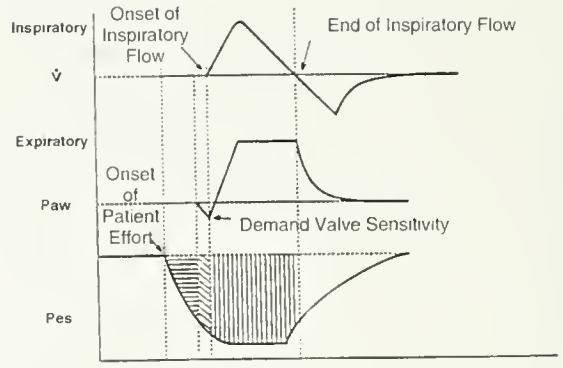

Fig. 27. The pressure-time product: The pressure-time product is an estimate of the oxygen consumption of the respiratory muscles. The shaded area includes work to overcome auto-PEEP (▤), work to trigger the demand valve (▨), and volume-pressure work (▥).

IN CONCLUSION

We have summarized many of the current uses of ventilator graphics and have analyzed flow and pressure traces to provide an introduction for a series of 'case histories' that can guide the clinician through the patient-ventilator assessment (or 'vent check') with a more systematic approach, using graphics as a tool.

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Jon Nilsestuen PhD RCP RRT, Robert Harwood MSA RRT, Ken Hargett BS RCP RRT, Section Editors. Submissions from readers are encouraged. Please follow the Manuscript Preparation Guide and submit to RESPIRATORY CARE Journal Office, 11030 Ables Lane, Dallas, Texas 75229.

Disaster Avoided? Cues from the Flow Signal

Ken Hargett BS RRT, Jon O Nilsestuen PhD RRT, and Steve Hayes BS RRT

Case Summary

A 39-year-old man received second and third degree burns over 70% of his body when the petroleum tanker that he was driving collided with a train and exploded in flames. He also received direct inhalational injury documented to extend into the major bronchi. The patient was intubated and placed on a Bear 1000 ventilator (Allied Healthcare Products Inc, St Louis MO). Acute respiratory distress syndrome (ARDS) and renal failure developed rapidly probably due to hypoperfusion-reperfusion injury. The ventilator was adjusted to deliver an 800-mL tidal volume (V_T) with positive end-expiratory pressure (PEEP). Because of his severe inhalational injury, he received an aerosolized mixture of acetylcysteine and heparin.

On Day 10, the patient was taken for debridement at which time the nasotracheal tube was replaced. Upon his return to the Burn Unit, he was placed back on the Bear 1000 but became agitated and appeared to be in great distress. The peak inspiratory pressure increased and reached the high pressure limit (50 cm H_2O). The hemoglobin saturation as measured by pulse oximetry did not change, but observation of the patient disclosed an active expiratory phase with marked use of accessory muscles.

The graphic display from the ventilator is shown in Figure 1. The deviations from the 'expected' in the display might lead one to suspect a malfunctioning flow transducer.

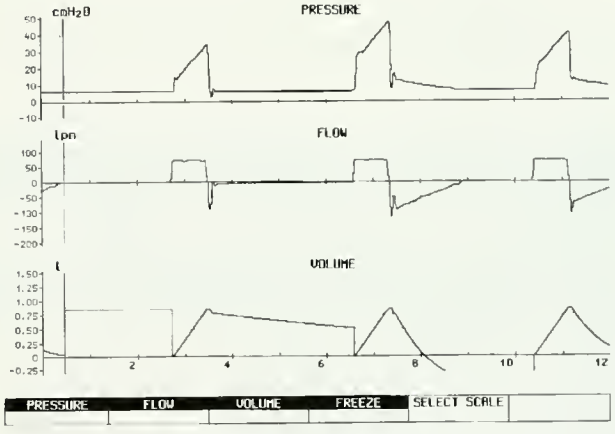

Fig. 1. Ventilator graphic from burn patient experiencing acute agitation and distress.

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How would you answer these questions?

In the first breath shown in Figure 1, which of the scalars appears abnormal?

How does the pressure component of the second breath differ from that of the first breath?

What is abnormal about the flow and volume waveforms in the second breath?

Answers and Discussion on page 1124

Answers

Abnormal scalars. The flow waveform suggests essentially no exhalation. The volume waveform shows that the exhaled portion of the waveform decays slowly and does not return to zero, indicating that little volume was exhaled. The pressure waveform is nearly normal; however, there is no apparent decrease in pressure during exhalation.

Second-breath pressure changes. The peak inspiratory pressure is much higher during the second breath, and during exhalation there is a 10-cm H_2O increase in pressure followed by a gradual fall to baseline after the initial exhalation.

Second-breath flow & volume abnormalities. The flow waveform shows a biphasic exhalation. The volume waveform shows more exhaled than inhaled volume as indicated by the expiratory portion of the volume trace, coursing below the zero baseline.

Analysis

The absence of an indication of expired volume on the first breath suggests a possible malfunction of the expiratory flow transducer, but because observation of the patient revealed active expiratory effort, immediate close inspection of the tracings was in order. In Figure 2 (an expanded flow and volume tracing from Figure 1) the flow tracing of the first breath indicates that apart from the initial expiratory flow spike, no expiratory flow is occurring. The second breath indicates a biphasic exhalation. The volume tracing on the first breath in Figure 1 indicates that no volume is being exhaled. The next breath shows an increase in peak inspiratory pressure and an exhaled volume that exceeds the volume inhaled with that breath (ie, the exhaled volume tracing continues below zero). The flow trace of the second breath initially spikes, flow reverses, and then returns to normal.

Fig. 2. Expanded view of flow and volume tracing from Figure 1.

The flow tracing is accompanied by a pressure tracing with similar biphasic characteristics—as flow reverses, pressure drops to zero and then returns to the expected (although somewhat prolonged) pressure decay pattern. Subsequent breaths show a similar pattern of increasing peak inspiratory pressure with biphasic exhalation and the volume tracing descending below the baseline.

Patient observation and waveform analysis suggested a potentially life-threatening condition—probable obstruction of the nasotracheal tube. The tracings suggest a partial ball-valve effect because inspiration is unimpeded but gas was completely trapped on one breath with slow exhalation against high resistance on the next. The increasing volume of trapped gas could lead to a pneumothorax or dislodging of the obstruction could lead to lobar obstruction and consequent collapse.[1]

The attending physician was immediately contacted, and the decision to perform a bronchoscopy was made. Bronchoscopy revealed a large flap of tissue with serous mucus attached, at the end of the tube. During inspiration the flap moved out of the way, only to occlude the tube during exhalation. Subsequent 'stacked' breaths accompanied by forced exhalation generated enough pressure to push the flap up into the nasotracheal tube and allow exhalation to occur. Visualization also revealed that the trachea ballooned out on inspiration and collapsed on exhalation. This increased compliance was thought to result from the extension of the burn injury into the airway.

The nasotracheal tube and the tissue flap were removed and a new tube carefully inserted. The patient tolerated the procedure well, and the tracings returned to normal. The patient survived his injuries and following a series of pseudomonas infections was weaned from the ventilator. After several surgeries for his burn injuries, he was discharged to a rehabilitation facility.

In Conclusion

This case highlights the usefulness of graphic display and analysis. Patients with inhalation injury are at risk for endotracheal tube occlusion from thick, stringy secretions and mucosal sloughing. Since the documentation of this case, we have observed another patient with a similar ball-valve mechanism that was recognized on graphic display and confirmed by immediate bronchoscopy.

Biphasic exhalation coupled with periodically rising peak pressure and breath stacking suggest partial obstruction. Close patient observation and waveform analysis can lead to prompt recognition and early intervention.

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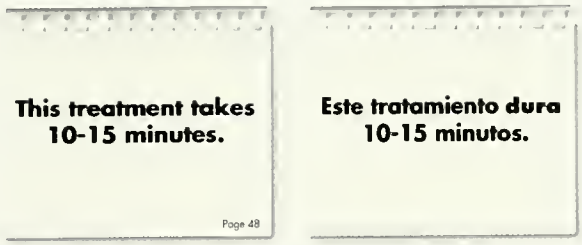

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Premature Infant Born by Emergency Cesarean Section

by Katherine A Douglas BEd RRT

Case Summary

Our high-risk team was summoned to the delivery room to attend an emergency cesarean section necessitated by overt umbilical cord prolapse in a hospitalized obstetric patient. The mother had experienced spontaneous rupture of membranes at 29 weeks gestation, 6 days prior to this event. This was the second pregnancy for the 34-year-old woman who had one living child. She was receiving ampicillin and was afebrile; she had not received corticosteroids during the hospitalization. There was no history of maternal drug or alcohol abuse. The patient had been treated for a Gardnerella infection (a Gram-negative, sexually transmitted organism) 4 months prior to delivery, but she had no positive cultures for any venereal infection during this hospital stay. Just prior to the mother's admission to the operating room, strong regular pulses were palpated in the protruding umbilical cord, but once in the operating suite, fetal heart tones were noted to be falling rapidly.

General anesthetic was administered, and the cesarean section was performed. A viable boy was delivered and immediately intubated with a 3.0-mm endotracheal tube (ETT) because he made no respiratory effort and his heart rate was < 80 b/min. However, his heart rate increased quickly with continuing manual ventilation. APGAR scores were 1 at 1 minute, and 8 at 5 minutes. The infant was appropriate for gestational age with a birthweight of 1.315 kg. Umbilical cord blood gas values are listed in Table 1.

Table 1. Infant's Umbilical Cord Blood Gas Values.

	P_{O_2}	P_{CO_2}	pH	Base Deficit
Venous	42	37	7.41	−0.3
Arterial	12	59	7.21	−5.5

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A catheter was inserted into the umbilical vein and blood was drawn for a complete blood count, blood glucose screening, and blood gas analysis. A bolus of 10 mL of plasma protein fraction (Plasmanate) was given. The baby was placed on a flow-triggered, time-cycled pediatric ventilator in the assist-control mode with settings: peak inspiratory pressure (PIP) = 20 cm H_2O, positive end-expiratory pressure = 5 cm H_2O, baseline ventilator rate of 50, and an inspiratory time of 0.3 seconds. $F_{DO_2} = 0.35$. The infant's hemoglobin saturation by pulse oximetry (S_{pO_2}) was 98% and the exhaled V_T 7.7 mL. The blood gas results showed: P_{O_2} 168 torr, P_{CO_2} 41 torr, pH 7.35, base deficit −2.5. PIP was decreased rapidly to 12 cm H_2O (exhaled V_T 5.7 mL) and F_{DO_2} was decreased to 0.21. The first chest radiograph is shown in Figure 1.

Fig. 1. Radiograph of infant who sustained umbilical cord prolapse and was delivered by cesarean section.

How would you answer these questions?

What are the positions of the ETT and venous catheter? Is the size of the ETT appropriate for this infant's gestational age and/or size?

Are any actions warranted with regard to the position of the ETT and catheter?

In light of this infant's gestational age, birthweight, and chest film, is administration of exogenous surfactant indicated? Why or why not?

Considering the reported blood gas results:

a. What are normal cord blood gas values? How do you explain the variance in these results (particularly the pH values)?

b. Because the P_{O_2} of the first extra-uterine blood gas is so high, how can you determine radiographically whether the umbilical catheter is in the vein and not in one of the umbilical arteries?

Answers and Discussion on page 1128

Answers

ETT & Venous Catheter Position: The ETT is positioned at the level of the third thoracic vertebra (T-3) and the tip of the umbilical venous catheter (UVC) is at T-6. The position of each device is acceptable and requires no change. The size of the tube is appropriate for this infant's weight.

Exogenous Surfactant Administration: In spite of this infant's gestational age (term is 40 weeks) and low birthweight, his lung fields are clear. Administration of exogenous surfactant is not indicated at this time.

Blood Gas Values: Normal cord blood gas values are shown in Table 2.[1] The high venous P_{O_2} and the borderline-acidotic arterial cord-blood gas values are consistent with cord compression. The position of an umbilical catheter may be determined radiographically by noting whether the catheter enters the inferior vena cava (UVC) or shows its characteristic descent into one of the leg loops before entering the aorta (arterial catheter). Figure 2 shows the transitional circulation involved.

Table 2. Normal Cord Blood Gases.[6] Values Are Means and Standard Deviations.

	P_{O_2}	P_{CO_2}	pH	Base Deficit
Venous	26 (5) torr	34 (6) torr	7.34 (0.03)	−1.3 (0.19)
Arterial	14 (5) torr	41 (8) torr	7.26 (0.05)	−1.6 (0.37)

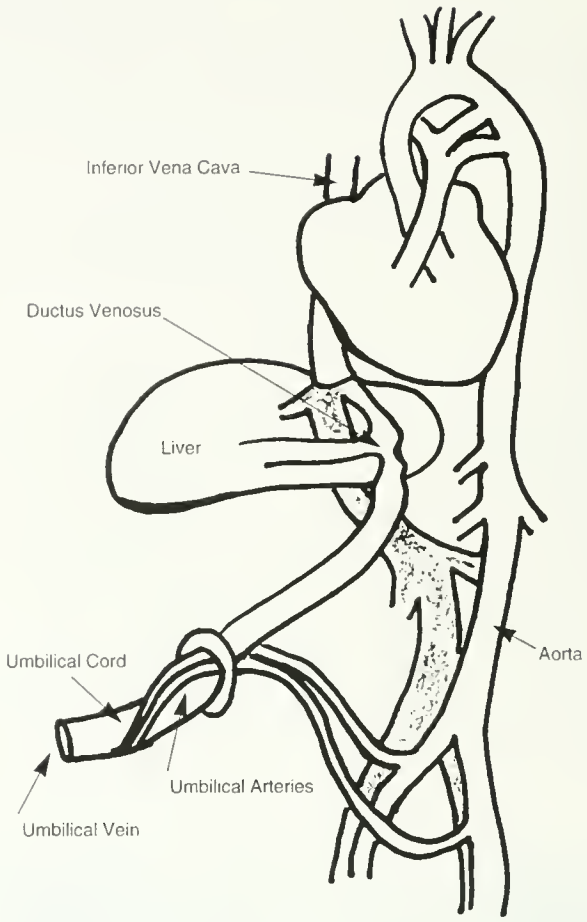

Fig. 2. Schema of the transitional circulation of the human infant.

Discussion

Cord prolapse is an acute event that is life-threatening to the fetus and is estimated to occur in 1 of every 200 pregnancies. By definition it is the protrusion of the umbilical cord into the lower uterine segment or vagina.[2] Because the cord is then vulnerable to entrapment and/or compression, immediate delivery by cesarean section is mandated to minimize the likelihood of fetal asphyxia and/or death.[2-4] In this patient the wide disparity between the umbilical venous pH and arterial pH is of concern despite the arterial pH > 7.2.[5] When cord compression occurs, the venous P_{O_2} may become 'hyperoxygenated' as blood flow to the fetus is reduced. Concurrently, the fetus, deprived of his lifeline of blood and oxygen, enters a state of respiratory acidosis and hypoxemia.[1,6]

When infants are born apneic, floppy, and bradycardic, so-called secondary apnea (ie, apnea that will not respond to tactile stimulation) must be assumed and aggressive steps taken,[7] regardless of the cause. Although apnea may herald prematurity, infection, respiratory distress syndrome, and other pathologies at birth, this infant's poor presentation was most likely due to the cord prolapse alone. His unremarkable chest radiograph and the subsequent negative cultures of his blood and tracheal secretions further supported this assessment.

Until radiographic confirmation is made, the acceptable position for the ETT is often estimated based on weight and the site of insertion (nasal or oral).[7,8] Infants who are large or small for gestational age or who have neck or thoracic anomalies may not fit neatly into these categories. However, until a chest film is made, auscultation of both sides of the chest in the axillae (to assure bilateral, equal air entry) and over the stomach must suffice. Unless central venous pressure monitoring is desired, acceptable UVC-tip position is above the diaphragm and below the heart.[9] Unlike a catheter in one of the umbilical arteries, the UVC is seen on radiograph to immediately ascend in the umbilical vein (Fig. 2).

Exogenous surfactant may be administered prophylactically before radiographic confirmation of the presence of respiratory distress syndrome (RDS) or in a rescue mode following radiographic confirmation. One of the concerns related to administering surfactant prior to inspection of the chest film is that some infants born early do not present with RDS. Therefore, they receive a medication that not only is unnecessary but also is expensive and not without risks.[10] The incidence of RDS in infants born at 29-30 weeks of gestation is between

60 and 70%.[11,12] For our patient, there was a reasonable possibility that surfactant administration would not be necessary. Awaiting the results of the initial chest film in this case was beneficial in terms of cost and the avoidance of unwarranted treatment. The infant was weaned from ventilatory support within 12 hours and had an uneventful hospital course. He was discharged at 46 days of age.

This case demonstrates that prudence in the administration of surfactant can be a wise and cost-saving decision for the low birthweight infant who may not have respiratory distress syndrome in spite of prematurity and a poor presentation at delivery.

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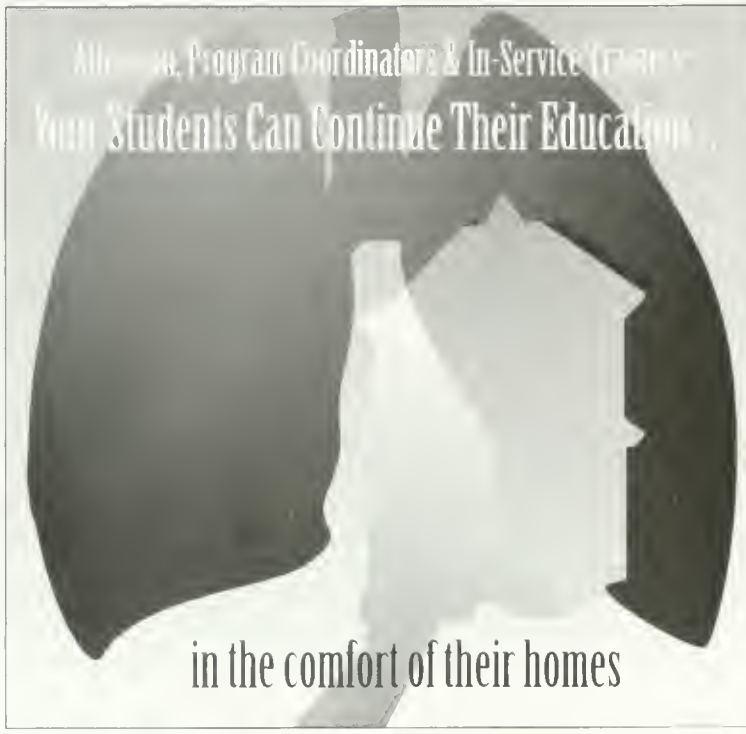

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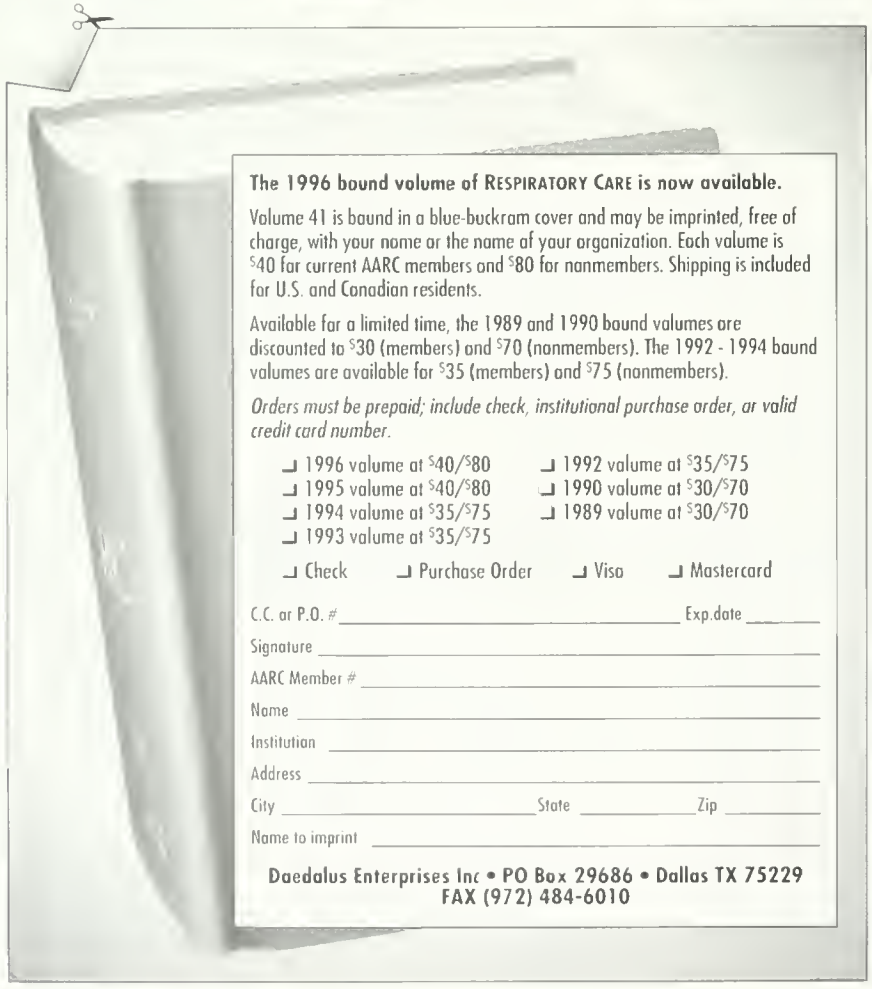

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A 47-Year-Old Woman with Cirrhosis and Hypoxemia

Raed A Dweik MD and James K Stoller MD

Case Summary

A 47-year-old woman with cryptogenic cirrhosis of the liver diagnosed 5 to 6 years earlier presented with dyspnea on exertion and blue coloration of the lips, which had been present for about 5 months. She denied a history of cough, fever, hemoptysis, or wheezing and had not experienced chest pain, palpitations, orthopnea, or swelling of the lower limbs. She has been a 1-pack/day smoker for 27 years. On physical examination, her blood pressure was 110/70 mm Hg, pulse 88 beats/min, and respiratory rate 16 breaths/min. The examination further revealed central cyanosis, digital clubbing, palmar erythema, and numerous cutaneous spider nevi. No jugular vein distention was noted, her lungs were clear to auscultation, and the results of the cardiac examination were normal. Abdominal examination revealed mild splenomegaly but no hepatomegaly or ascites. The results of analysis of an arterial blood sample drawn with the patient sitting at rest and breathing room air, spirometry, and diffusing capacity are shown in Table 1.

Table 1. Room-Air Blood Gas, Spirometry, and Diffusing Capacity Values for 47-Year-Old Woman with Cirrhosis, Blue Lips, and Dyspnea on Exertion*

Test	Variable	Value
Arterial blood gas analysis (sample)	pH	7.51
	P_{CO_2}	26 torr
	P_{O_2}	44 torr
	S_{aO_2}	82%
Spirometry	FVC	3.66 L (101% predicted)
	FEV_1	2.89 L (105% predicted)
	FEV_1/FVC	0.79
Diffusing capacity	D_{LCO-sb}	6.75 L · torr · min^{-1} (32% predicted)

*Blood drawn with patient sitting

Dr Dweik and Dr Stoller are members of the staff in the Department of Pulmonary Care and Critical Care Medicine, Cleveland Clinic Foundation, Cleveland, Ohio.

How would you answer these questions?

What is your diagnosis?

What other test(s) would you suggest?

Answers and Discussion on page 1132

Answers

Diagnosis. This patient has the classic features of the hepatopulmonary syndrome, which include the triad of liver disease, increased alveolar-arterial difference for oxygen when breathing room air, and evidence of intravascular pulmonary dilatations.[1] The presence of moderate-to-severe hypoxemia in a patient with hepatic dysfunction should lead to consideration of this diagnosis.

Recommended Tests. Clinical features of the hepatopulmonary syndrome include signs and symptoms of hepatic and respiratory disease. Most patients present with signs and symptoms of chronic liver disease, including gastrointestinal bleeding, esophageal varices, ascites, palmar erythema, spider nevi, and splenomegaly.[2] Pulmonary features include tachypnea, digital clubbing, dyspnea, platypnea (an increase in shortness of breath induced by assuming the upright position that is relieved by lying down) and orthodeoxia (a decline in P_{aO2} $\geq$ 10 torr or 10% upon assuming an upright posture that is relieved by recumbency).[2,3] To support the diagnosis of the hepatopulmonary syndrome, confirm the presence of orthodeoxia, and quantitate the presence and degree of pulmonary shunting, arterial blood samples were obtained from the patient while she was sitting and standing and breathing room air and 100% oxygen (Table 2).

Table 2. Standing and Supine Blood Gas Values and Results of Shunt Study in Patient Suspected of Hepatopulmonary Syndrome.

Variable	Supine Position	Standing Position
pH	7.46	7.49
P_{CO_2}	28 torr	25 torr
P_{O_2} (room air)	61 torr	42 torr
S_{aO_2} (room air)	89%	72%
P_{O_2} (100% O_2)	473 torr (10% shunt)	85 torr (26.5% shunt)

Discussion

Patients with end-stage liver disease may have various abnormalities of pulmonary function, including a restrictive pattern, air flow obstruction, impairment of diffusing capacity, and a widened alveolar-arterial difference.[4-6] The most common pulmonary function abnormality in patients with end-stage liver disease is a reduction in diffusing capacity of the lung.[4] Patients with the hepatopulmonary syndrome also have low values for diffusing capacity, but their lung volumes and expiratory flows remain normal if they do not have coexisting obstructive or restrictive pulmonary disease from other causes.[3] Mild hypoxemia is also common among cirrhotic patients who do not have the hepatopulmonary syndrome, but severe hypoxemia (P_{aO2} < 60 torr) in a cirrhotic patient without associated cardiopulmonary disease strongly suggests the hepatopulmonary syndrome.[3]

Vascular abnormalities referred to as intrapulmonary vascular dilatations are thought to be the major cause of impaired gas exchange in the hepatopulmonary syndrome. The expanded size of the dilated capillaries allows some of the hemoglobin in erythrocytes to pass through the pulmonary circulation without coming in contact with alveolar air (Fig. 1[7]). Giving supplemental oxygen enhances oxygenation more

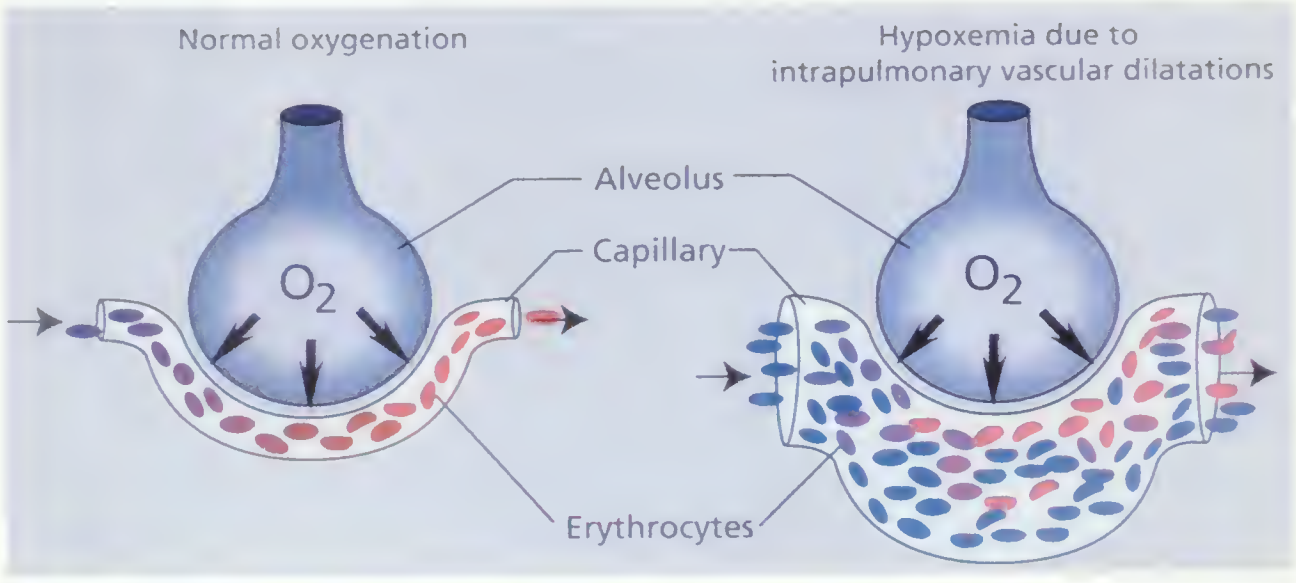

Fig. 1. Left: in a normal pulmonary capillary, almost all of the hemoglobin in erythrocytes can become oxygenated. Right: Intrapulmonary vascular dilatations as in the hepatopulmonary syndrome, allow erythrocytes to traverse the capillary bed without becoming fully oxygenated. (Reproduced from Reference 7, with permission.)

than would be expected with true 'anatomic' shunt because the driving pressure for oxygen across the dilated pulmonary capillary increases.[8]

The cause of the hepatopulmonary syndrome remains unknown although several mechanisms have been postulated, including failure of the damaged liver to clear pulmonary vasodilators, production by the damaged liver of a circulating vasodilator, and inhibition by the damaged liver of a circulating vasoconstrictive substance.[3] Contrast-enhanced 'bubble' echocardiography is the preferred test to confirm right-to-left shunting and can also differentiate intrapulmonary from intracardiac shunts. The results of medical therapy for the hepatopulmonary syndrome have been disappointing. If a patient has severe hypoxemia ($P_{aO2} < 55$ torr while breathing room air) or desaturation with activity (< 92%), supplemental oxygen is indicated. Various therapies have been tried without great success, including pharmacologic strategies, plasma exchange, and attempted occlusion of intrapulmonary vascular dilatations. Some reversal of the hepatopulmonary syndrome have been reported following liver transplantation, but the resolution of hypoxemia has not been universal, keeping the role of liver transplantation for the treatment of hepatopulmonary syndrome controversial and in need of further study.[9,10]

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RESPIRATORY CARE

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January 1997

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Reflecting on 40 Years of RESPIRATORY CARE:

The Lighter Side

fun (fun), *n.* 1. something that provides mirth or amusement 2. enjoyment or playfulness

Throughout the years, funny things have happened on our way to the press. Some of them were planned and others, much to our chagrin, were not. Enjoy this month's reflections—because "a merry heart does good like a medicine."

"But it says detergent here!"

Bug? Yes. Insect? No.

In response to the letter describing a 'foreign body' in a ventilator circuit[1]—a spider is not an insect.

David J Pierson MD
Medical Director, Respiratory Care
Harborview Medical Center
Professor of Medicine
University of Washington
Seattle, Washington

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The editor responds:

My oversight, Dr Pierson! Allow me to quote an appropriate (?) bit from Shakespeare's *A Midsummer Night's Dream.*

Weaving spiders come not here;
Hence, you long-legg'd spinners, hence!
Beetles black, approach not near;
Worm nor snail, do no offence.

Pat Brougher BA RRT
Editor, RESPIRATORY CARE
Dallas, Texas
[Respir Care 1992;37(10):1211]

My Doctor told me to stay away from cigarettes

Baggers, Not Beggars

AAAARGGHH!! In my intubation letter published in August,[1] a typo changed "Silent, obedient baggers" to "beggars."

Ah, well, I guess Baggers can't be choosers.

Tom Burns RRT
Phoenix, Arizona

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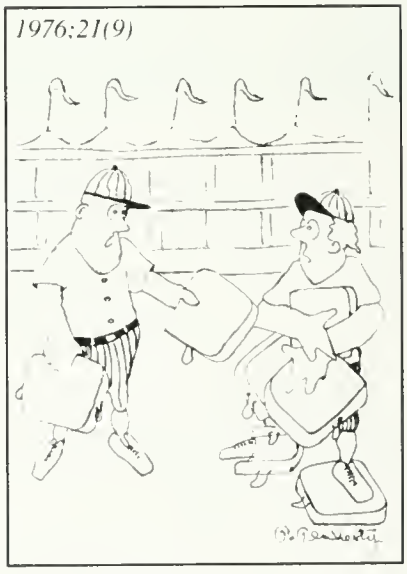
[Respir Care 1992;37(10):1211]



If you continue to steal bases, we're just going to have to increase the base excess!

The Day of the Initial, or Who Cares about the V.D. to V.T. Ratio?

Though long past initial day,
So far we are from that Day One—

(Past primal time, our spring we say,
When race we run was just begun),
Still wed we are to lettered title,
Initials are what all pursue,
Lettered no, but letters vital,
Follow words that tell you're you.

I.T. now R.T.'s become,
An R.T. isn't A.R.T.
A.R.T. though art to some
Needs an I. for quality.
C.I. and an I.T. had
It's day, but I. got changed to R.
and O.J. with an S. is glad
But O.J.T. soon falls from par.

J.R.C.I.T.E. is
Euphonious to some,
But with an R. instead of I.
It would a JERC become,
So let's remember when O.J.
We use a Y. or T.
Improper made connections may
Cause increase in V.D.

—H F Helmholz
['Pressure Drop' in Respir Care 1974; 19(10):8]

"...Everyone set? ...
Branberry will lead off, Wilkenstein
and Barlof join in with 1:2 I.E. time."

Big Wind

A therapist caught in a freeze
Was later required to sneeze.
From up through his larynx
He cleared out his pharynx
And started a sizable breeze.

Bob Cornelius
Gainesville, Florida

Bennett-diction

An aspiring lawyer named Jennet
Hoped someday to sit in the Senate
But he smoked as he pleased
Till he coughed and he wheezed
So instead he stays home with his Bennett.

Bob Cornelius
Gainesville, Florida
[Both poems appeared in 'Pressure Drop,' Respir Care 1976;21(9):886.]

Hmm ... just as I thought ...
aspirated peanuts!

Editor As Death Dealer

During my time as an editor of this Journal, I loved my work except for one task. I hated writing letters of rejection to authors. I often felt like a death dealer aiming at a probably fragile ego. That one author felt the same way was revealed early this year (January 1996), when I received a letter from a person whose paper I had rejected 4 years ago. "It felt like an arrow through my heart," he wrote. But he went on to thank me for having saved him from probable embarrassment if his flawed work had been published.

All this reminds me of an incident that occurred several years back when I was flying from San Francisco to New York. The fellow in the next seat spent the first hour or so of our imprisonment lovingly engaged with papers from his briefcase—reading them, talking to them, writing in their margins. At last he put the papers away. Then, although I had not said a word to him, he began telling me about his work and about himself as the performer of that work. To me it was dull stuff—insurance or the like—and I did not encourage him. After a long time he stopped. Then, sensing the imbalance he had created, he gave me my chance, asking me the Great American Question: "And what do *you* do?

This made me uncomfortable. I am shy, diffident, snobbish. I did not want to talk. I did not wish to say, "I am an editor" and then be asked the polite, pro-forma questions about what an editor does, etc. How could I reply in a way to staunch the flow of conversation?

After a moment I knew what to do. I could identify an aspect of my occupation without using the word "editor." Staring straight ahead (if I had looked at the guy I might have burst out laughing), I said, slowly and dis-tinct-ly, "I am a trained killer."

Silence reigned for the rest of the flight.

Phil Kittredge
Journal Editor, 1968-1993
Little River, California
[Respir Care 1996;41(2):142]

Doctor, there is definitely something
wrong with this patient.

Contributions to this section are welcome. Send double-spaced typed material (and illustrations if pertinent) to Historical Notes, RESPIRATORY CARE, 11030 Ables Lane, Dallas TX 75229-4593. Identify source of material and include your name, credentials, and address.

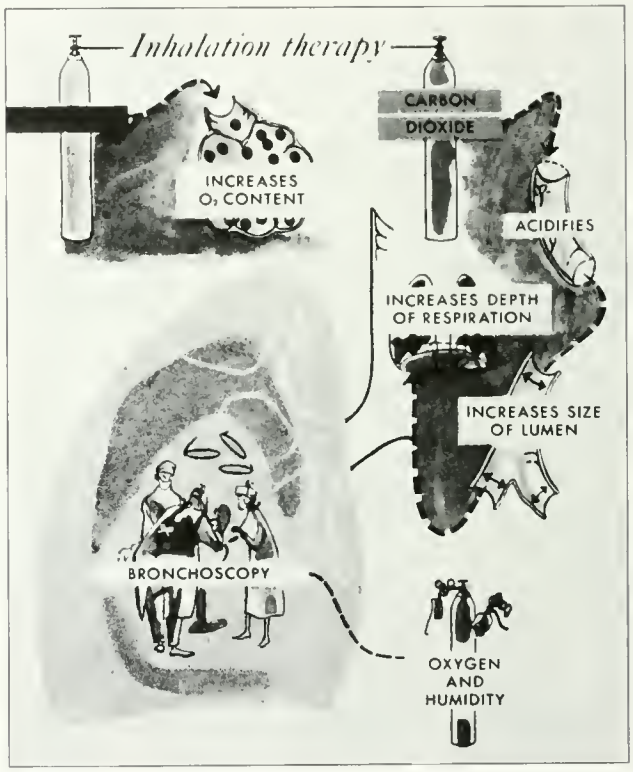
Effective Inhalation Therapy: Local Obstruction

Obstruction of a single bronchus or localized groups of bronchi may fall into several categories. It may be complete or incomplete obstruction. It may be of sudden occurrence or gradual development and it may involve major or smaller bronchi or bronchioles.

It is perfectly obvious that an obstruction of the trachea or one of the major bronchi will cause very serious disturbance in both the oxygen absorption of the patient and his feeling of well being. On the other hand, the obstruction of small bronchi, if not too many of them are involved, may occur without too many symptoms and its discovery may be accidental. The degree of symptoms, therefore, will depend upon the amount of lung which is served by the bronchus involved and the therapy will frequently be dictated by this same factor.

Complete obstruction of a bronchus produces a picture that is uniform and a train of events that follow a regular pattern. This is true whether the symptoms are severe or absent, since these will depend on the amount of lung involved alone. In order to understand what happens when the bronchus is obstructed it is necessary to remember three things. First, that it is a function of the lung to absorb gas. Second, that even if the bronchus has been obstructed and the ventilation in this area completely stopped, the circulation continues for a considerable period of time. Third, that the lung is an elastic body in which there is a strong tendency to contraction and collapse. Associated with this are two opposing forces, one for expansion and one for collapse, and when the balance is disturbed a change in the state of the lung occurs.

Remembering this we shall look at the changes occurring with bronchial obstruction. Once the obstruction is complete, air can neither get in nor get out. The gas in the alveoli roughly represents a mixture of 15 per cent oxygen, 6 per cent CO_2, and 79 per cent nitrogen. The circulating blood will absorb oxygen rapidly until the percentage, or rather the pressure of oxygen is equal to that in the circulating venous blood which is entering the pulmonary capillaries. At this time one finds about 5 per cent oxygen, 6 per cent CO_2, and the remainder nitrogen; but the volume has been decreased by the absorption of oxygen, and the elastic alveolus has decreased in size. Since the blood continues to circulate, and since the alveolus tends to contract, there will be constant absorption of the remaining gas, most of which is nitrogen. This is slow, requiring eight to twelve hours until all of the gas in the involved alveoli has been absorbed. At this time there is no longer any air space remaining. If the obstruction has been completely aseptic and non-irritating,



Treatment of localized bronchial obstruction requires bronchoscopy and inhalation therapy to remove the obstruction and maintain adequate ventilation of the alveoli.

From **Effective Inhalation Therapy**, written by Edwin R Levine MD in cooperation with Alvan L. Barach MD, J Winthrop Peabody MD, and Maurice Segal MD, and published in 1953 by the National Cylinder Gas Co of Chicago. Dr Levine, a chest physician, was an early champion of our profession and President of the American Association for Inhalation Therapy in 1952 (the only physician in the Association's history to so serve). The other authors were also pioneers in pulmonary medicine and inhalation therapy.

This excerpt was made available to RESPIRATORY CARE by Teri Nikolai Wilson RRT RPFT, The Children's Medical Center, Dayton, Ohio.

then that area of lung will look like fetal lung, with all of the cells close to each other and no space in between. This, however, seldom if ever happens, and the result of the complete absorption of the gas is an airless lung area in which, however, some fluid exists in the alveolar space either by exudation or by transudation.

At this time we have an area of lung in which circulation may still go on but into which no air and thus no oxygen can enter. The result is that the blood which passes through this region returns from the lung exactly as it came, and we have the phenomena of venous blood having passed through airless lung being mixed with the arterial blood which has been aerated.

During this time what has been happening to the patient? When the bronchus becomes obstructed, if this bronchus is large enough, he will show a sudden picture of shock, dyspnea, cyanosis, and have an elevation in temperature. When major bronchi are involved it may also be noted that one side or one part of his chest does not move during respiration. It is customary in such cases because of the great dyspnea to use oxygen, but it must be clearly understood that, if the obstruction is complete, you cannot improve the patient's condition much by simply increasing the percentage of oxygen in the inspired air. As a result he is disappointed when neither the cyanosis or dyspnea improve under oxygen. The treatment is removal of the obstruction and for this bronchoscopy is the method of choice.

Great assistance and sometimes removal of the obstruction can be accomplished by proper inhalation therapy, generally the inhalation of CO_2 and oxygen mixtures, preferably 95 per cent oxygen to 5 per cent CO_2. Although in most cases there may be some retention of CO_2 in the body, the inhalation produces different effects. Inspiration becomes much deeper. Since increasing the depth of respiration is associated with increased size of the bronchial lumen, such therapy may result in some gas getting past the obstruction. Once gas is behind the obstruction there is some chance that all or a part of the obstructing material may be expelled on cough. When no gas is behind the obstruction, the most severe cough will not dislodge it because the expulsion depends upon the blast of air. If with each inspiration of a little gas manages to get past the obstruction, enough may accumulate to expel some part of the obstructing material on subsequent cough. This will result in a partially cleared airway and may represent the beginning of the elimination of the obstruction.

A second property of CO_2 which is extremely valuable here must not be overlooked. If, as is many times the case, the obstruction is mucus or bronchial secretion alone, the viscosity of this mucus maintains the barrier. The material is generally alkaline and if it can be made more acid the viscosity will be diminished. The mucus will tend to break up or flow and the obstruction will be relieved. Since CO_2 goes into the solution as an acid, the effect on the obstructing bronchial secretion is that of acidifying and diminishing of viscosity, and so aids in removal of the barrier.

Since the removal of the obstruction, when it can be removed, is the proper method of treating atelectasis, only supportive inhalation measures should be used when bronchoscopy is to be done. Such measures are oxygen alone by mask or by catheter, and following the bronchoscopy, the continuation of the inhalation treatment. There are no advantages to the use of CO_2 under such circumstances and the possible effect of increasing the acid balance in the blood may be avoided. It is, however, necessary to emphasize that the inhaled gas be properly humidified to avoid the recurrence of obstruction which may follow the drying of the bronchial secretion.

Since the normal expulsive mechanism of the bronchi, cough, ciliary action, muscular movements, are needed to get rid of accumulating secretion, it follows that no medicine should be given which tends to abolish or decrease any of these mechanisms. It is sometimes felt that if enough oxygen is given it is safe to use small quantities of morphine or codeine or similar substances. This may be true as regards the effects on the respiratory center but oxygen has no effect on the expulsive mechanisms of the bronchial tree and thus cannot counteract any diminishing of their function by drugs.

The symptoms and clinical picture discussed above occur when one of the larger bronchi are obstructed. If an obstruction occurs in the small bronchi the same physiologic changes take place in the alveoli, but not enough of them may be involved to produce symptoms. Unless enough infection is present to produce a picture of toxicity, the patient may be completely unaware of his bronchial obstruction, and it may be found only by x-ray. If multiple small bronchi are obstructed, the total lung volume may be sufficient to produce as many and as severe symptoms as if a major bronchus was obstructed.

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Happy Holidays

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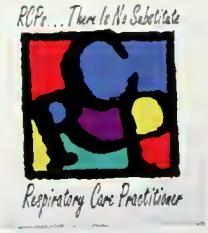

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What is tracheal pressure-triggering—and do we need it? no! we don't need it [Branson] **41(6):526** *point of view*
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Work of breathing and pressure-time product on pressure support ventilation, continuous positive airway pressure, and T-piece [Patel et al] **41(11):1013** *research article*

1997 Call for Abstracts

RESPIRATORY CARE • OPEN FORUM

The American Association for Respiratory Care and its science journal, RESPIRATORY CARE, invite submission of brief abstracts related to any aspect of cardiorespiratory care. The abstracts will be reviewed, and selected authors will be invited to present posters at the OPEN FORUM during the AARC International Convention and Exhibition in New Orleans, Louisiana, December 6-9, 1997. Accepted abstracts will be published in the November 1997 issue of RESPIRATORY CARE. Membership in the AARC is not required for participation.

SPECIFICATIONS—READ CAREFULLY!

An abstract may report **(1) an original study, (2) the evaluation of a method, device or protocol, or (3) a case or case series.** Topics may be aspects of adult acute care, continuing care/rehabilitation, perinatology/pediatrics, cardiopulmonary technology, or health care delivery. The abstract may have been presented previously at a local or regional—but not national—meeting and should not have been published previously in a national journal. The abstract is the only evidence by which the reviewers can decide whether the author should be invited to present a poster at the OPEN FORUM. Therefore, *the abstract must provide all important data, findings, and conclusions*. Give specific information. Do not write such general statements as "Results will be presented" or "Significance will be discussed."

Essential Content Elements

Original study. Abstract *must* include (1) Background: statement of research problem, question, or hypothesis; (2) Method: description of research design and conduct in sufficient detail to permit judgment of validity; (3) Results: statement of research findings with quantitative data and statistical analysis; (4) Conclusions: interpretation of the meaning of the results.

Method, device, or protocol evaluation. Abstract *must* include (1) Background: identification of the method, device, or protocol and its intended function; (2) Method: description of the evaluation in sufficient detail to permit judgment of its objectivity and validity; (3) Results: findings of the evaluation; (4) Experience: summary of the author's practical experience or a lack of experience; (5) Conclusions: interpretation of the evaluation and experience. Cost comparisons should be included where possible and appropriate.

Case report. Abstract *must* report a case that is uncommon or of exceptional educational value and must include (1) Introduction: Relevant basic information important to understanding the case. (2) Case Summary: Patient data and response, details of interventions. (3) Discussion: Content should reflect results of literature review. The author(s) should have been actively involved in the case and a case-managing physician must be a co-author or must approve the report.

Abstract Format and Typing Instructions

Accepted abstracts will be photographed and reduced by 40%; therefore, the size of the original text should be *at least* 10 points. A font like Helvetica or Geneva makes the clearest reproduction. The first line of the abstract should be the title in all capital letters. Title should explain content. Follow title with names of all authors (including credentials), institution(s), and location; underline presenter's name. Type or electronically print the abstract *single spaced in a single paragraph in the space provided on the abstract blank*. Insert only one letter space between sentences. Text submission on diskette is encouraged but must be accompanied by a hard copy. Identifiers will be masked (blinded) for review. Data may be submitted in table form, *and simple figures may be included provided they fit within the space allotted.* No figures, illustrations, or tables are to be attached to the abstract form. Provide all author information requested. A clear photocopy of the abstract form may be used. Standard abbreviations may be employed without explanation; new or infrequently used abbreviations should be spelled out on first use. Any recurring phrase or expression may be abbreviated, if it is first explained. Check the abstract for (1) errors in spelling, grammar, facts, and figures; (2) clarity of language; and (3) conformance to these specifications. An abstract not prepared as requested may not be reviewed. Questions about abstract preparation may be telephoned to the editorial staff of RESPIRATORY CARE at (972) 406-4667.

Deadline Allowing Revision

Authors may choose to submit abstracts early. Abstracts postmarked by March 17, 1997 will be reviewed and the authors notified *by letter only* to be mailed by April 25, 1997. Rejected abstracts will be accompanied by a written critique that should, in many cases, enable authors to revise their abstracts and resubmit them by the final deadline (May 27, 1997).

Final Deadline

The mandatory Final Deadline is May 27, 1997 (postmark). Authors will be notified of acceptance or rejection *by letter only*. These letters will be mailed by August 15, 1997.

Mailing Instructions

Mail (Do not fax!) 2 clear copies of the completed abstract form, diskette (if possible), and a stamped, self-addressed postcard (for notice of receipt) to:

RESPIRATORY CARE OPEN FORUM
11030 Ables Lane
Dallas TX 75229-4593

1997 Respiratory Care Open Forum

Abstract Form

18.8 cm or 7.4"

13.9 cm or 5.5"

1. Title must be in all upper case (capital) letters, authors' full names and text in upper and lower case.
2. Follow title with all authors' names including credentials (underline presenter's name), institution, and location.
3. Do not justify (ie, leave a 'ragged' right margin).
4. **Do not use type size less than 10 points.**
5. All text, tables, and figures must fit into the rectangle shown.
6. Submit 2 clean copies. This form may be photocopied if multiple abstracts are to be submitted.

Mail original & 1 photocopy (along with postage-paid postcard) to

Respiratory Care Open Forum
11030 Ables Lane
Dallas TX 75229-4593

Early deadline is March 17, 1997 (postmark)

Final deadline is May 27, 1997 (postmark)

Presenter

Name & Credentials

Mailing Address

Voice Phone & Fax

Corresponding Author If Different from Presenter

Name & Credentials

Mailing Address

Voice Phone & Fax

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

Page _ of _

Form Approved OMB No 0910-0291 Expires 4/30/96
See OMB statement on reverse

FDA Use Only (Resp Care)

Triage unit sequence #

A. Patient information

1 Patient identifier
In confidence

2 Age at time of event:
or
Date of birth:

3 Sex
☐ female
☐ male

4 Weight
_____ lbs
or
_____ kgs

B. Adverse event or product problem

1. ☐ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
☐ death (mo/day/yr)
☐ life-threatening
☐ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other

3. Date of event (mo/day/yr)

4 Date of this report (mo/day/yr)

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)
#1
#2

2. Dose, frequency & route used
#1
#2

3 Therapy dates (if unknown, give duration) (from/to or best estimate)
#1
#2

4 Diagnosis for use (indication)
#1
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6 Lot # (if known)
#1
#2

7 Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9 NDC # (for product problems only)
– –

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1 Brand name

2 Type of device

3. Manufacturer name & address

4 Operator of device
☐ health professional
☐ lay user/patient
☐ other

5. Expiration date (mo/day/yr)

6
model #
catalog #
serial #
lot #
other #

7 If implanted, give date (mo/day/yr)

8 If explanted, give date (mo/day/yr)

9 Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1 Name & address

phone #

2 Health professional?
☐ yes ☐ no

3 Occupation

4 Also reported to
☐ manufacturer
☐ user facility
☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500 1/96)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- you're not certain the product caused the event
- you don't have all the details

Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling
- therapeutic failures

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 to report by phone or for more information
- 1-800-822-7967 for a VAERS form for vaccines

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

The public reporting burden for this collection of information has been estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS Reports Clearance Office
Paperwork Reduction Project (0910-0291)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

An agency may not conduct or sponsor and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number

Please do NOT return this form to either of these addresses.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • Food and Drug Administration

FDA Form 3500-back

Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH
The FDA Medical Products Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

American Association for Respiratory Care Membership Application

Please read the eligibility requirements for each of the classifications in the right-hand column, then complete the applicable section. All information requested below must be provided, except where indicated as optional. See other side for more information and fee schedule. Please sign and date application on reverse side and type or print clearly. Processing of application takes approximately 15 days.

- ☐ Active
- Associate
  - ☐ Foreign
  - ☐ Physician
  - ☐ Industrial
- ☐ Special
- ☐ Student

Last Name _____

First Name _____ Middle _____

Social Security No. _____

Home Address _____

City _____

State _____ Zip __ __ __ __ __ - __ __ __ __

Phone No. (_____) _____

Primary Job Responsibility (check one only)

- ☐ Technical Director
- ☐ Assistant Technical Director
- ☐ Pulmonary Function Specialist
- ☐ Instructor/Educator
- ☐ Supervisor
- ☐ Staff Therapist
- ☐ Staff Technician
- ☐ Rehabilitation/Home Care
- ☐ Medical Director
- ☐ Sales
- ☐ Student
- ☐ Other, specify _____

Type of Business

- ☐ Hospital
- ☐ Skilled Nursing Facility
- ☐ DME/HME
- ☐ Home Health Agency
- ☐ Educational Institution
- ☐ Manufacturer or supplier
- ☐ Other, specify _____

Date of Birth (optional) _____ Sex (optional) _____

U.S. Citizen? ___ Yes ___ No

Have you ever been a member of the AARC? _____

If so, when? From _____ to _____

Preferred mailing address: ☐ Home ☐ Business

FOR ACTIVE MEMBER

An individual is eligible if he/she lives in the U.S. or its territories or was an Active Member prior to moving outside its borders or territories, and meets ONE of the following criteria (1) is legally credentialed as a respiratory care professional if employed in a state that mandates such, OR (2) is a graduate of an accredited educational program in respiratory care, OR (3) holds a credential issued by the NBRC. An individual who is an AARC Active Member in good standing on December 8, 1994 will continue as such provided his/her membership remains in good standing.

Place of Employment _____

_____

Address _____

City _____

State _____ Zip __ __ __ __ __ - __ __ __ __

Phone No. (_____) _____

Medical Director/Medical Sponsor _____

FOR ASSOCIATE OR SPECIAL MEMBER

Individuals who hold a position related to respiratory care but do not meet the requirements of Active Member shall be Associate Members. They have all of the rights and benefits of the Association except to hold office, vote, or serve as chair of a standing committee. The following subclasses of Associate Membership are available: Foreign, Physician, and Industrial (individuals whose primary occupation is directly or indirectly devoted to the manufacture, sale, or distribution of respiratory care equipment or supplies). Special Members are those not working in a respiratory care-related field.

PLEASE USE THE ADDRESS OF THE LOCATION WHERE YOU PERFORM YOUR JOB, NOT THE CORPORATE HEADQUARTERS IF IT IS LOCATED ELSEWHERE.

Place of Employment _____

_____

Address _____

City _____

State _____ Zip __ __ __ __ __ - __ __ __ __

Phone No. (_____) _____

FOR STUDENT MEMBER

Individuals will be classified as Student Members if they meet all the requirements for Associate Membership and are enrolled in an educational program in respiratory care accredited by, or in the process of seeking accreditation from, an AARC-recognized agency.

SPECIAL NOTICE — Student Members do not receive Continuing Respiratory Care Education (CRCE) transcripts. Upon completion of your respiratory care education, continuing education credits may be pursued upon your reclassification to Active or Associate Member.

School/RC Program _____

_____

Address _____

City _____

State _____ Zip __ __ __ __ __ - __ __ __ __

Phone No. (_____) _____

Length of Program

- ☐ 1 year
- ☐ 2 years
- ☐ 4 years
- ☐ Other, specify_____

Expected Date of Graduation (REQUIRED INFORMATION)

Month_____ Year_____

American Association for Respiratory Care • 11030 Ables Lane • Dallas, TX 75229-4593 • (972) 243-2272 • Fax (972) 484-2720

American Association for Respiratory Care Membership Application

Demographic Questions

We request that you answer these questions in order to help us design services and programs to meet your needs.

Check the Highest Degree Earned

- ☐ High School
- ☐ RC Graduate Technician
- ☐ Associate Degree
- ☐ Bachelor's Degree
- ☐ Master's Degree
- ☐ Doctorate Degree

Number of Years in Respiratory Care

- ☐ 0-2 years
- ☐ 3-5 years
- ☐ 6-10 years
- ☐ 11-15 years
- ☐ 16 years or more

Job Status

- ☐ Full Time
- ☐ Part Time

Credentials

- ☐ RRT
- ☐ CRTT
- ☐ Physician
- ☐ CRNA
- ☐ RN
- ☐ LVN/LPN
- ☐ CPFT
- ☐ RPFT
- ☐ Perinatal/Pediatric

Salary

- ☐ Less than $10,000
- ☐ $10,001-$20,000
- ☐ $20,001-$30,000
- ☐ $30,001-$40,000
- $40,001 or more

PLEASE SIGN

I hereby apply for membership in the American Association for Respiratory Care and have enclosed my dues. If approved for membership in the AARC, I will abide by its bylaws and professional code of ethics. I authorize investigation of all statements contained herein and understand that misrepresentations or omissions of facts called for is cause for rejection or expulsion.

A yearly subscription to **Respiratory Care** journal and **AARC Times** magazine includes an allocation of $6.50 from my dues for each of these publications.

NOTE: Contributions or gifts to the AARC are not tax deductible as charitable contributions for income tax purposes. However, they may be tax deductible as ordinary and necessary business expenses subject to restrictions imposed as a result of association lobbying activities. The AARC estimates that the nondeductible portion of your dues - the portion which is allocable to lobbying - is 26%.

Signature _____

Date _____

Membership Fees

Payment must accompany your application to the AARC. Fees are for 12 months. (NOTE: Renewal fees are $65.00 Active, Associate-Industrial or Associate-Physician, or Special status; $80.00 for Associate-Foreign status; and $35.00 for Student status.)

☐ Active	$77.50
☐ Associate (Industrial or Physician)	$77.50
☐ Associate (Foreign)	$92.50
☐ Special	$77.50
☐ Student	$35.00
TOTAL	$_____

Specialty Sections

Established to recognize the specialty areas of respiratory care. The sections publish a newsletter four times a year that focuses on issues of specific concern to that specialty. The sections also design the specialty programming at the national AARC meetings.

☐ Adult Acute Care Section	$ 5.00
☐ Education Section	$10.00
☐ Perinatal-Pediatric Section	$ 5.00
☐ Diagnostics Section	$ 5.00
☐ Continuing Care-Rehabilitation Section	$ 5.00
☐ Management Section	$10.00
☐ Transport Section	$ 5.00
☐ Home Care	$ 5.00
☐ Subacute Care	$ 5.00
TOTAL	$_____

GRAND TOTAL = Membership Fee plus optional sections $_____

☐ Total Amount Enclosed $_____

☐ Please charge my dues (see below)

To charge your dues, complete the following:

- ☐ MasterCard
- ☐ Visa

Card Number

__ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __

Card Expires _____/_____

Signature _____

Mail application and appropriate fees to:

American Association for Respiratory Care • 11030 Ables Lane • Dallas, TX 75229-4593 • (972) 243-2272 • Fax (972) 484-2720

Not-for-profit organizations are offered a free advertisement of up to eight lines to appear, on a space-available basis, in Calendar of Events in RESPIRATORY CARE. Ads for other meetings are priced at $5.50 per line and require an insertion order. Deadline is the 20th of the month two months preceding the month in which you wish the ad to run. Submit copy and insertion orders to Calendar of Events, RESPIRATORY CARE, 11030 Ables Lane, Dallas TX 75229-4593.

Calendar of Events

AARC & AFFILIATES

January 29–31—Oregon Society

Annual Pacific Northwest Respiratory Care Conference at the Monarch Hotel and Conference Center, Clackamas, Oregon.
Manufacturers and vendors are scheduled to exhibit.
Exhibitors Contact: Tami Carter at (503) 626-9947
Information Contact: Irene Iwata-Morgan at (503) 494-6158

January 31—Texas Society

Annual Winter Forum in Austin, Texas
Contact: TSRC Executive Offices, PO Box 515239, Dallas TX 75251, (972) 680-2455.

February 2–5—American College of Chest Physicians (ACCP) and the AARC

Cardiopulmonary Wellness & Rehabilitation meeting in Snowbird, Utah.
Contact: Arlene Karavich, ACCP, 3300 Dundee Rd, Northbrook IL 60062, (847) 498-8358, fax (847) 498-5460.

April 24–25—Respiratory Care Services of Arkansas Children's Hospital and the Arkansas Society

Diamond Conference in Little Rock, Arkansas
In addition to the Conference, luncheon tutorials are available.
Contact: Mike Anders at (501) 320-4782, Kathy Boyle at (501) 320-3535, fax (501) 320-3411, or visit the Internet page at http://www.ach.uams.edu/announce/diamond

OTHER MEETINGS

January 31—Penobscot Bay Medical Center

The Respiratory Care Department presents the 8th Annual Respiratory Care Conference at Samoset Resort, Rockport, Maine
The Conference benefits Camp Opportunity and Respiratory Care Education; the $35 registration fee includes lunch and all materials.
Contact: Conference Chair Janey Barthelette at (207) 596-8485.

Mark Your Calendars!

Future AARC Conventions

December 6-9, 1997
New Orleans, Louisiana

November 7-10, 1998
Atlanta, Georgia

AARC Summer Forum

July 25-27, 1997
Phoenix, Arizona

July 17-19, 1998
Naples, Florida

New Products & Services

News releases about new products and services will be considered for publication in this section. There is no charge for these listings. Send descriptive release and glossy black and white photographs to RESPIRATORY CARE Journal, New Products and Services Dept, 11030 Ables Lane, Dallas TX 75229-4593. The Reader Service Card immediately follows the authors & advertisers index at the back of the Journal.

BLOOD ANALYSIS SYSTEM. Diametrics Medical Inc® releases the AVOXimeter 4000, a battery-operated, portable system for comprehensive CO-oximetry measurements. The AVOXimeter is designed for use with the IRMA Blood Analysis System. The company claims that the AVOXimeter measures total hemoglobin concentration, oxyhemoglobin, carboxyhemoglobin, and calculated oxygen content. The analyzer uses small samples (50 μL) and provides results at the bedside in 10 seconds. The AVOXimeter also features an electronic quality control program to ensure calibration and accuracy. For more information, circle Reader Service Number 160.

NITROUS OXIDE MONITOR. CEA Instruments Inc offers the PM-300 Nitrous Oxide (NO_2) Monitor. The unit is an AC/DC portable, lightweight, continuous infrared analyzer designed to monitor NO_2 delivery systems. The monitor features an operating range of 0-100 (± 1)%, the company claims. The unit is equipped with a built-in sample pump, digital readout to the first decimal place, recorder output, rechargeable battery, and low-battery signal. Equipment warm-up is < 3 minutes, and the unit is designed to operate for at least 8 hours before recharging is necessary. Circle Reader Service Number 161 for more details.

HAND-HELD PULSE OXIMETER. BCI International adds the Model 3303 Hand-Held Pulse Oximeter. According to the company, the portable oximeter has alarms, an internal rechargeable battery, optional DC-DC converter, a sleep mode feature for overnight monitoring, and a recorder for data collection. The data can later be transferred to a printer or personal computer for further analysis. The unit is fully portable and can be used for continuous or spot-checks of pulse oximetry. Details are available, circle Reader Service Number 162.

DIRECTIONAL STYLET. Zipper Medical Inc supplies the Schroeder Oral/Nasal Directional Stylet. The Stylet is designed for dynamic directional control of the tip of an endotracheal tube for use in routine or difficult intubation, direct laryngoscopy, or blind nasal intubation. By using the proximal thumb control, the distal tip can be flexed. The stylet is made of a disposable plastic and is available in 2 adult sizes. For details about the stylet, circle Reader Service Number 163.

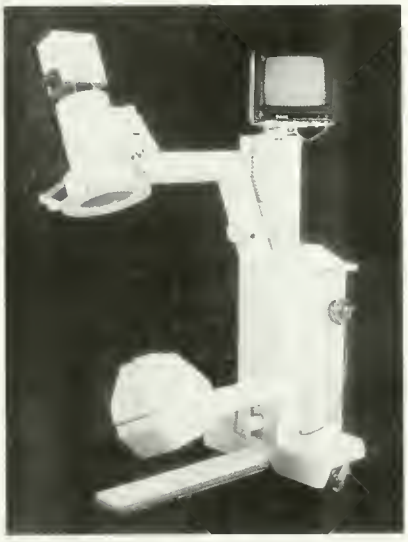
BREATHING CIRCUIT COMPONENTS. Ferraris Medical Inc supplies 100% latex-free breathing circuit components—fluted breathing bags, face masks, and corrugated tubing. Each product, claims the manufacturer, is made of reusable, synthetic rubber, neoprene and EPDM—both latex-free components that offer durability and eliminate potential latex reactions. Circle Reader Service Number 164 for details.

UPDATED PRACTICE MANAGEMENT SOFTWARE. DB Consultants Inc advances its Practice Management Software Modules including Managed Care Supplement, Custom Reports, SOAP Notes, and Electronic Claims System (in both the NSF and ANSI 837 formats) to the Windows 95 platform. The new products are being offered to more than 6,000 existing users, the company says.

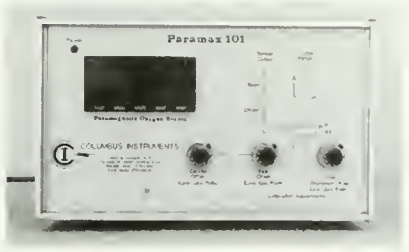
The new design optimizes operation with Microsoft's Windows95™ graphic user interface and works with a variety of word processing and spreadsheet systems. Billing modules and other options are available; for details, circle Reader Service Number 165.

STOPCOCKS. Hi-Flo Stopcocks are included in the products offered by Spectra Medical Devices Inc. The stopcocks, 0.100 minimum bore I.D., are manufactured from quality medical-grade plastic for reliability and consistency, the company says. The stopcocks are available in 1-way, 3-way, and 4-way with or without rotating Luer locks, with low- or high-profile handles, and are compatible with gamma and ETO Sterilization. The products are 501K approved. Circle Reader Service Number 166 for more information.

CORDLESS COMPRESSOR-NEBULIZER SYSTEM. PARI debuts its Walkhaler™, a compressor-nebulizer system designed for easy transport. According to company literature, the unit, suitable for asthma, chronic obstructive pulmonary disease, or cystic fibrosis patients, is a small ultrasonic device with the reliability of a compressor system. The Walkhaler delivers treatments in 8 to 10 minutes, is adequate for long outings or day trips, and has a removable, rechargeable battery that delivers up to 4 treatments/charge. Additional batteries are available; however, the internal battery recharges in about 4 hours. The unit includes the compressor, PARI LC Plus Reusable Nebulizer, a carrying case, 115V AC charger adapter, and a 1-year limited warranty. For details, circle Reader Service Number 167.



MOBILE FLUOROSCOPIC SYSTEM. International Biomedical Inc presents AccUview mobile C-arm fluoroscopy system. The rotating arm provides a versatile system for performing pacemaker insertions, swallow studies, urodynamic analysis, orthopedic, pulmonary, and endoscopic procedures, according to International Biomedical. The self-contained unit is lightweight and maneuverable, ideally suited for the hospital and mobile scanning services. In addition, the system offers an image intensifier, thermal or film printer, and videocassette recorder interface. Circle Reader Service Number 168 for information about available options.



OXYGEN ANALYZER. The Paramax-101—a paramagnetic oxygen analyzer—is now available from Columbus Instruments International Corporations. The analyzer offers accurate and stable oxygen analysis with 0.001% O_2 resolution for environmental and physiological applications, Columbus says. The unit measures the magnetic susceptibility of oxygen gas, can be calibrated to detect from 0-100% O_2 resolution, and has a built-in temperature-controlled chamber and air-sample pump. The Paramax also features a sensor with 0-5V or ± 5V outputs. Circle Reader Service Number 169 for more information.

CART. Andonian Cryogenics Inc inaugurates the lightweight aluminum cart into its line of products. The cart—used for transporting various sizes of liquid oxygen reservoirs—features extended height, a ratchet safety strap, and built-in stair climber. The company says that the cart is suitable for home health care providers. For information from Andonian, circle Reader Service Number 170.

Notices

Notices of competitions, scholarships, fellowships, examination dates, new educational programs, and the like will be listed here free of charge. Items for the Notices section must reach the Journal 60 days before the desired month of publication (January 1 for the March issue, February 1 for the April issue, etc). Include all pertinent information and mail notices to RESPIRATORY CARE Notices Dept, 11030 Ables Lane, Dallas TX 75229-4593.

The American Respiratory Care Foundation Publication Awards for 1996

Radiometer Awards for Best Features

(Three winners, $333 each)

Cardiorespiratory Interactions—The Role of Echocardiography in the Practice of Respiratory Care—A Resai Bengur, Jon N Meliones, James W NeSmith, Michele E Kappeler, and Jennifer S Li. [Respir Care 1996;41(3):215-225]

Test Your Radiologic Skill—Right Paratracheal Density in an Asymptomatic Patient—Luis Teba and N LeRoy Lapp. [Respir Care 1996;41(6):544-547]

PFT Corner—Lessons from Spirometry: Look at the Picture—Matthew Veatch, Jaek Wanger, and Edward Chan. [Respir Care 1996;41(8):745-747]

GlaxoWellcome 1996 OPEN FORUM Awards

Best Papers based on OPEN FORUM Presentations by Those Who Have Never Published as First Author
(Two winners, $500 each)

Accuracy of Electrolyte and Blood Gas Determinations from Samples Collected in Preheparinized Syringes—Virginia M Haver, William Eng, John Douglas Hussey, Daniel D Bankson, and Sambasiva Lakshminarayan. [Respir Care 1996;41(9):805-808]

Regulation of Pressurization Rate Reduces Inspiratory Effort during Pressure Support Ventilation: A Bench Study—Massimo Croci, Paolo Pelosi, Davide Chiumello, and Luciano Gattinoni. [Respir Care 1996;41(10):880-884]

Best Paper Based on an OPEN FORUM Presentation
($1,000)

Evaluation of a Commercial Standard for Checking Pulse Oximeter Performance—Teresa A Volsko, Robert L Chatburn, and Thomas J Kallstrom. [Respir Care 1996;41(2):100-104]

Best Paper Published in RESPIRATORY CARE

Original Study, Evaluation, or Case Report
($1,000)

A Respiratory Care Assessment-Treatment Program: Results of a Retrospective Study—Kevin L Shrake, John E Scaggs, Kevin R England, Joseph Q Henkle, and Lanie E Eagleton. [Respir Care 1996;41(8):703-713]

Dr Allen DeVilbiss Technology Paper Award

Best Paper addressing a new technology or a new application of current technology in respiratory care
($2,000 cash plus travel expenses to the AARC Annual International Convention & Exhibition to receive the award)

Comparison of Three Humidification Techniques during Mechanical Ventilation: Patient Selection, Cost, and Infection Considerations—Richard D Branson, Kenneth Davis Jr, Richard Brown, and Mitchell Rashkin. [Respir Care 1996;41(9):809-816]

NBRC & AARC Team Up To Offer Database

The National Board for Respiratory Care (NBRC) and the American Association for Respiratory Care (AARC) have jointly developed the National Respiratory Care Disciplinary Database. The database is a repository for final disciplinary actions taken against respiratory care practitioners by state licensure agencies (disciplinary actions are considered final after all appeals have been exhausted; pending actions or appeals are not maintained in the database). Information in the database is provided by state licensure agencies that have an agreement with the NBRC and the AARC. These agencies notify the NBRC when action is cleared or reinstatement occurs. The database is offered to third-party payers, hospitals, insurance companies, education programs, and other business entities who have a direct interest or need to know such information.

Know the Area Code for AARC: 972

Please note our new area code:
Phone: (972) 243-2272
Fax: (972) 484-2720 or (972) 484-6010

Note: If you're having difficulty reaching us at this area code—call your local long-distance provider.

New Internet Site

A new Internet site connects users to up-to-the-minute information from the Food and Drug Law Institute. The site, available through the Center for Devices and Radiological Health (CDRH) Home Page, provides the Current Good Manufacturing Practice (CGMP) requirements set forth in *Medical Devices; CGMP Final Rule*; and *Quality System Regulation* [docket 90N-0172]. The information includes text, graphics, and files; device safety alerts; Federal Register reprints; pre-market submissions information; small manufacturers' assistance; video conferencing and electronic submissions; and more device-oriented information. Access the Internet site via the Food and Drug Administration's Home Page at

http://www.fda.gov

or contact the CDRH at

http://www.fda.gov/cdrh/index.html

Helpful Web Sites

American Association for Respiratory Care
http://www.aarc.org

National Board for Respiratory Care
http://www.nbrc.org

The National Board for Respiratory Care—1997 Examination Dates and Fees

Examination	Examination Date	Examination Fee	
CRTT Examination	March 8, 1997 Application Deadline: January 1, 1997	$ 100 60	(new applicant) (reapplicant)
	July 12, 1997 Application Deadline: May 1, 1997	100 60	(new applicant) (reapplicant)
	November 8, 1997 Application Deadline: September 1, 1997	100 60	(new applicant) (reapplicant)
RRT Examination	June 7, 1997 Application Deadline: February 1, 1997	100 60	Written only (new applicant) Written only (reapplicant)
		110	CSE only (all applicants)
	December 6, 1997 Application Deadline: August 1, 1997	210 170	Both (new applicant) Both (reapplicant)
CPFT Examination	June 7, 1997 Application Deadline: April 1, 1997	110 80	(new applicant) (reapplicant)
RPFT Examination	December 6, 1997 Application Deadline: September 1, 1997	160 130	(new applicant) (reapplicant)
Perinatal/Pediatric Respiratory Care Specialty Examination	March 8, 1997 Application Deadline: November 1, 1996	160 130	(new applicant) (reapplicant)

For information about other services or fees, write to the National Board for Respiratory Care, 8310 Nieman Road, Lenexa KS 66214, or call (913) 599-4200, FAX (913) 541-0156, email nbrc-info@nbrc.org.

RESPIRATORY CARE

Manuscript Preparation Guide

General Information

RESPIRATORY CARE welcomes original manuscripts related to respiratory care and prepared according to these Instructions. Manuscripts are blinded and reviewed by professionals who are experts in their fields. Authors are responsible for all aspects of the manuscript and receive galleys to proofread before publication. Each accepted manuscript is copyedited so that its message is clear and it conforms to the Journal's style. Published papers are copyrighted by Daedalus Inc and may not be published elsewhere without permission.

Editorial consultation is available at any stage of planning or writing. On request, specific guidance is provided for all publication categories. These Instructions and related materials are available. Write to RESPIRATORY CARE, 11030 Ables Lane, Dallas TX 75229-4593, call (972) 243-2272, or fax (972) 484-6010.

Publication Categories & Structure

Research Article: A report of an original investigation (a study). It includes a Title Page, Abstract, Introduction, Methods, Results, Discussion, Conclusions, Product Sources, Acknowledgments, References, Tables, Appendices, Figures, and Figure Captions.

Evaluation of Device/Method/Technique: A description and evaluation of an old or new device, method, technique, or modification. It has a Title Page, Abstract, Introduction, Description of Device/Method/Technique, Evaluation Methods, Evaluation Results, Discussion, Conclusions, Product Sources, Acknowledgments, References, Tables, Appendices, Figures, and Figure Captions.

Case Report: A report of a clinical case that is uncommon, or was managed in a new way, or is exceptionally instructive. All authors must be associated with the case. A case-managing physician must either be an author or furnish a letter approving the manuscript. Its components are Title Page, Abstract, Introduction, Case Summary, Discussion, References, Tables, Figures, and Figure Captions.

Review Article: A comprehensive, critical review of the literature and state-of-the-art summary of a pertinent topic that has been the subject of at least 40 published research articles. Title Page, Outline, Introduction, Review of the Literature, Summary, Acknowledgments, References, Tables, Appendices, and Figures and Captions may be included.

Overview: A critical review of a pertinent topic that has fewer than 40 published research articles.

Update: A report of subsequent developments in a topic that has been critically reviewed in this Journal or elsewhere.

Point-of-View Paper: A paper expressing personal but substantiated opinions on a pertinent topic. Title Page, Text, References, Tables, and Illustrations may be included.

Special Article: A pertinent paper not fitting one of the foregoing categories may be acceptable as a Special Article. Consult with the Editor before writing or submitting such a paper.

Editorial: A paper drawing attention to a pertinent concern; it may present an opposing opinion, clarify a position, or bring a problem into focus.

Letter: A signed communication about prior publications in this Journal or about other pertinent topics. Tables and illustrations may be included. Mark "For publication."

Blood Gas Corner: A brief, instructive case report involving blood-gas values—with Questions, Answers, and Discussion.

Drug Capsule: A mini-review paper about a drug or class of drugs that includes discussions of pharmacology, pharmacokinetics, and pharmacotherapy.

Graphics Corner: A brief case report incorporating waveforms for monitoring or diagnosis—with Questions, Answers, and Discussion.

Kittredge's Corner: A brief description of the operation of respiratory care equipment—with information from manufacturers and editorial comments and suggestions.

PFT Corner: Like Blood Gas Corner, but involving pulmonary function tests.

Cardiorespiratory Interactions. A case report demonstrating the interaction between the cardiovascular and respiratory systems. It should be a patient-care scenario; however, the case—the central theme—is the systems interaction. CRI is characterized by figures, equations, and a glossary. See the March 1996 issue of RESPIRATORY CARE for more detail.

Test Your Radiologic Skill: Like Blood Gas Corner, but involving pulmonary medicine radiography and including one or more radiographs, may involve imaging techniques other than conventional chest radiography.

Review of Book, Film, Tape, or Software: A balanced, critical review of a recent release.

Preparing the Manuscript

Print on one side of white bond paper, 8.5 in. x 11 in. (216 x 279 mm) with margins of at least 1 in. (25 mm) on all sides of the page. Use ***double-spacing*** throughout the ***entire*** manuscript. Use

a standard font (eg, Times, Helvetica, or Courier) at least 10 points in size, and do not use italics except for special emphasis. Number all pages in upper-right corners. Indent paragraphs 5 spaces. Do ***not justify***. Do ***not*** put authors' names or other identification anywhere except on the title page. Repeat title only (no authors) on the abstract page. Begin each of the following on a new page: Title Page, Abstract, Text, Product-Sources List, Acknowledgments, References, each Table, and each Appendix. Use standard English in the first person and active voice.

Center main section headings on the page and type them in capital and small letters (eg, Introduction, Methods, Results, Discussion). Begin subheadings at the left margin and type them in capital and small letters (eg, Patients, Equipment, Statistical Analysis).

References. Cite only published works as references. Manuscripts accepted but not yet published may be cited as references: designate the accepting journal, followed by (in press). Please provide 3 copies of the in-press article for reviewer inspection. Cite references in the text with superscript numerals. Assign numbers in the order that references are first cited. On the reference page, list the cited works in numerical order. Follow the Journal's style for references. Abbreviate journal names as in *Index Medicus*. List all authors.

Article in a journal carrying pagination throughout volume:

1. Rau JL, Harwood RJ. Comparison of nebulizer delivery methods through a neonatal endotracheal tube: a bench study. Respir Care 1992;37(11):1233-1240.

Article in a publication that numbers each issue beginning with Page 1:

2. Bunch D. Establishing a national database for home care. AARC Times 1991;15(Mar):61,62,64.

Corporate author journal article:

3. American Association for Respiratory Care. Criteria for establishing units for chronic ventilator-dependent patients in hospitals. Respir Care 1988;33(11):1044-1046.

Article in journal supplement: (Journals differ in their methods of numbering and identifying supplements. Supply sufficient information to promote retrieval.)

4. Reynolds HY. Idiopathic interstitial pulmonary fibrosis. Chest 1986;89(3, Suppl):139S-143S.

Abstract in journal: (Abstracts citations are to be avoided. Those more than 3 years old should not be cited.)

5. Stevens DP. Scavenging ribavirin from an oxygen hood to reduce environmental exposure (abstract). Respir Care 1990;35(11): 1087-1088.

Editorial in journal:

6. Enright P. Can we relax during spirometry? (editorial). Am Rev Respir Dis 1993;148(2):274.

Editorial with no author given:

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8. Aelony Y. Ethnic norms for pulmonary function tests (letter). Chest 1991;99(4):1051.

Paper accepted but not yet published:

9. Hess D. New therapies for asthma. Respir Care (year, in press).

Personal author book: (For any book, specific pages should be cited whenever possible.)

10. DeRemee RA. Clinical profiles of diffuse interstitial pulmonary disease. New York: Futura, 1990:76-85.

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11. American Medical Association Department of Drugs. AMA drug evaluations, 3rd ed. Littleton CO: Publishing Sciences Group, 1977.

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